

EPA Registration No.
39967-137
Vol. 1

U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs

OCT 16 1996

ANTEC INTERNATIONAL LTD.
C/O DR ALAN WAGNER, DVM, MS
2821 RIVER PARK DR
COLUMBUS, OH 43220

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your transmittal of 10/09/96. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

We are unable to accept your data submittal for further processing and review, because of the significant deficiencies noted below. It is being returned to you for correction. If deficiencies were found which apply to your overall submission, they are described immediately following this paragraph. If problems are found with individual studies, they are described below linked to the study identifier found on the enclosed copy of your bibliography.

Studies 01 - 04 were all rejected for the following reasons/s:

* You failed to sign the statement of data confidentiality claims included in the study.

A statement of compliance or non-compliance with the Good Laboratory Practices Standards contained in 40 CFR160 is required for all studies (except range finding studies and supplements to previously submitted studies) submitted to EPA. This statement must appear as page 3 of all studies, and must be signed and dated by the study sponsor, the study submitter, and the study director. Please see 40 CFR 160.12 for specific guidance.

Studies 03 - 04 were all rejected for the following reasons/s:

* Your Statement of No Data Confidentiality Claims is contradicted by the marking(s) on page(s) 3 of the study. If you do not intend to make Supplemental

Claims of Data Confidentiality you can explicitly
override these markings when you resubmit this study.

DR. ALAN R. WAGNER
Regulatory Affairs and Technical Services

Private Consultant
Clinical Investigations

2821 River Park Drive
Columbus, Ohio 43220

Ph: 614/459-5965
Fax: 614/459-9875

October 8, 1996

Document Processing Desk (Amendment)
Mr. Walter C. Francis
Acting Product Manager (PM 32)
Antimicrobial Program Branch
Registration Division (H7505C)
Environmental Protection Agency
Room 248, Crystal Mall II
1921 Jefferson Davis Highway
Arlington, VA 22202

Re: Submittance of Amendment for Updating and Revision
of Labeling for our formulation, Virkon-S
EPA Registration No. 62432-1

Dear Mr. Francis:

Please find attached an Application Amendment for Updating and Revision of Labeling for Our Formulation, Virkon-S (EPA Number 62432-1).

This amendment follows the approval by the agency of our revised labeling of June 26, 1996 in accordance with the letter of March 7, 1996 from Mrs. Ruth Douglas.

The attached application for updating and revising our Virkon S labeling concerns an expansion of our efficacy claims based upon the recent completion of studies by laboratories in accordance with AOAC and GLP standards.

Also, please find enclosed as an attachment, supportive data for VIRKON-S claims for animal application and egg sanitizing as described in the proposed labeling.

The supportive data for the claims identified in the labeling is listed in the attachment as follows:

- (1) Investigation to Test the Effect of Prolonged Spraying of Livestock With Virkon-S *Rejected Study (01)*
- (2) Trials in Poultry With a Sprayed Disinfectant - Virkon-S *Rejected Study (02)*
- (3) Eye Irritation Study in the Rabbit - Virkon-S (1.0% W/V) *Rejected Study (03)*
- (4) Skin Irritation and Corrosivity Study in the Rabbit - Virkon-S (1.0% W/V) *Rejected Study (04)*

Mr. Walter C. Francis
Acting Product Manager (32)
Page 2

We appreciate your advice and assistance in the preparation and submissions of previous applications to your division, Mr. Francis, and will be looking forward to your review, comments and approval of this application.

Respectfully submitted,

Dr. Alan R. Wagner

Dr. Alan R. Wagner, D.V.M., M.Sc.
Agent for Antec International Ltd.

ARW/mw

VIA CERTIFIED MAIL - 3 copies

cc: Mr. Francis Auchincloss
Antec International Ltd.

Reviewer ID

DEM/SME

Submission No.

5512980

Data Package No. _____

CODING FORM FOR APPLICATIONS FOR REGISTRATION/AMENDMENTS

File Symbol/Reg. No. 62432-1 PM 32 Action Code 300[10] Descriptor (Amend/Resubmissions only) Final 1-601[5] Intrastate Call-in ☐ (Y) Yes ☒ (N) No [15] Child-resistant Packaging ☐ (C) Certification ☐ (S) Service Person

[20] Registration Type:

☒ (1) Conditional ☐ (2) Unconditional☐ (R) Non-residential Use Only☐ (N) Not-Applicable

[25] Proposed Classification: [30] Final Classification:

☐ (R) Restricted ☐ (R) Restricted☐ (G) General ☐ (N) Not Classified

[35] Date on Application:

[04] EPA Received Date:

[40] Date Received by PM

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MO DAY YR0 7 0 1 9 6
MO DAY YR0 7 1 1 9 6
MO DAY YR

[80] Method of Support:

☐ (1) Cite-All ☐ (6) Owner Submission☐ (4) Not Applicable ☐ (7) Total Submission☐ (5) Not Submitted ☐ (8) Selective Method

Reviewers Requested:

DATE
SENTDUE
DATEDATE
RETURNEDRESPONSE
CODERESPONSE
DATE

CH

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[115] FINAL Response
ACTION Code 37

[120] Response

0 7 1 1 9 6
MO DAY YR75-DAY RESPONSE DUE DATE: ☐ (Y) Yes☐ (N) No

DR. ALAN R. WAGNER
Regulatory Affairs and Technical Services

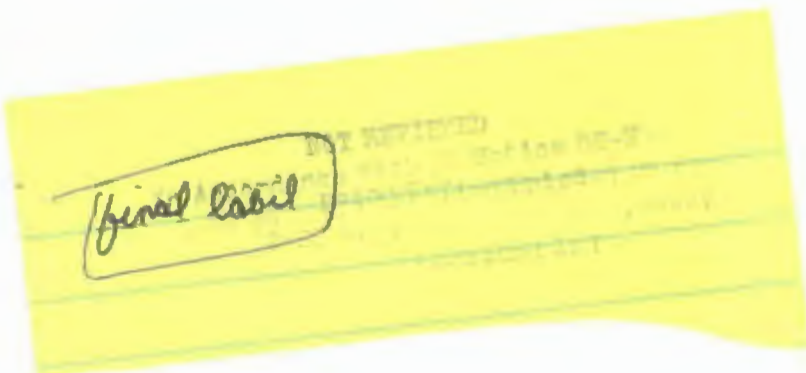
Private Consultant
Clinical Investigations

2821 River Park Drive
Columbus, Ohio 43220

Ph: 614/459-5965
Fax: 614/459-9875

July 1, 1996

Document Processing Desk (Amendment)
Mr. Walter C. Francis
Acting Product Manager (PM 32)
Antimicrobial Program Branch
Registration Division (H7505C)
Environmental Protection Agency
401 M Street SW
Washington, DC 20460



Attn: Mr. Robert Travaglini

Re: Virkon S
EPA Registration No. 62432-1
Resubmission of May 22, 1996
and Submission of Finished Labeling

Dear Mr. Travaglini:

In accordance with our telephone conversation and your letter of June 26, 1996 regarding this subject, please find enclosed as requested, one copy of the finished labeling before releasing the product for shipment.

Thank you for your concern regarding the location of the application and your excellent assistance of expediting the sending of the approved labeling.

I hope to have the opportunity to meet with you during my next visit to Washington, D.C. and please give my best regards to Mr. Francis.

Sincerely,

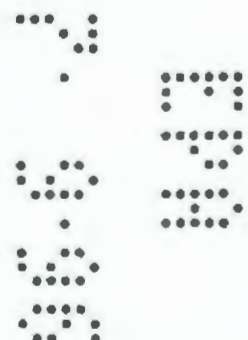
Alan R. Wagner

Alan R. Wagner, D.V.M., M.S.
Agent for Antec International Ltd.

ARW/mw

VIA CERTIFIED MAIL

cc: Francis Auchincloss
Antec International Ltd.



Reviewer ID

TRANAGLINI

Submission No.

S 507679

Data Package No.

CODING FORM FOR APPLICATIONS FOR REGISTRATION/AMENDMENTS

File Symbol/Reg. No. 102432-1 PM 32 Action Code 30110 Descriptor (Amend/Resubmissions only) Amend Labeling5 Intrastate Call-in ☐ (Y) Yes ☐ (N) No 15 Child-resistant Packaging ☐ (C) Certification ☐ (S) Service Person20 Registration Type:☐ (1) Conditional ☐ (2) Unconditional☐ (R) Non-residential Use Only☐ (N) Not-Applicable25 Proposed Classification: 30 Final Classification:☐ (R) Restricted ☐ (R) Restricted
☐ (G) General ☐ (N) Not Classified35 Date on Application: 04 EPA Received Date: 40 Date Received by PM:
MO DAY YR MO DAY YR MO DAY YR
6 24 96 6 25 96 6 26 9680 Method of Support:☐ (1) Cite-All ☐ (6) Owner Submission
☐ (4) Not Applicable ☐ (7) Total Submission
☐ (5) Not Submitted ☐ (8) Selective Method

Reviewers Requested:

CH
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PL
DEB
NDEB
TB
EEB
EFGB

DATE SENT	DUE DATE	DATE RETURNED	RESPONSE CODE	RESPONSE DATE

115 FINAL Response ACTION Code 17120 Response JUN 26 1996
MO DAY YR75-DAY RESPONSE DUE DATE: ☐ (Y) Yes ☐ (N) No

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

JUN 26 1996

Antec International Limited
Chilton Industrial Estate
Sudbury, Suffolk CO10 6XD
England

Attn: Dr. Alan Wagner, D.V.M., M.S.
Authorized U.S. Agent for Antec International Ltd.

Subject: Virkon S
EPA Registration No. 62432-1
Your Resubmission of May 22, 1996

The submitted product labeling, revised in accordance with EPA's letter of March 7, 1996 has been reviewed and the following comments apply.

- The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable. A stamped copy is enclosed for your records. Submit one copy of the finished labeling before releasing the product for shipment.

- You are reminded that although supportive data for non-human related claims do not have to be submitted to the Agency, you are required to have satisfactory data in your files for these claims and to be able to provide it to the Agency upon request.

If you should have any questions concerning this letter, you may call Robert Travaglini on (703) 305-6909.

Sincerely,

R. J. Francis

Walter C. Francis
Acting Product Manager (32)
Antimicrobial Program Branch
Registration Division (7505C)

SYMBOL	7505C							
SURNAME	Travaglini							
DATE	6-26-96							



VirKon.S

BROAD SPECTRUM DISINFECTANT

For Use in Cleaning and Disinfecting Industrial
Animal and Agricultural Facilities

EFFECTIVE AGAINST

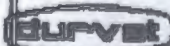
BACTERIA	
<i>Streptococcus pyogenes</i> , <i>Staphylococcus aureus</i> , <i>Mycobacterium tuberculosis</i> , <i>Escherichia coli</i> , <i>Salmonella typhimurium</i> , <i>Salmonella choleraesuis</i> , <i>Pseudomonas aeruginosa</i> , <i>Staphylococcus epidermidis</i> , <i>Mycobacterium fortuitum</i> , <i>Bordetella pertussis</i> , <i>Pseudomonas mallei</i> , <i>Campylobacter pylori</i> , <i>Clostridium perfringens</i> , <i>Acinetobacter baumannii</i> , <i>Tetragona lyodysenteriae</i> , <i>Bordetella pertussis</i>	
VIRUSES OF	
Polio virus, Swine influenza, Influenza parvovirus, Rotavirus diarrhoea, Vaccinia virus, Pseudotuberculosis, PRRS (Porcine Reproductive & Respiratory Syndrome), African Swine Fever	
FUNGI	
<i>Aspergillus niger</i> , <i>Aspergillus fumigatus</i> , <i>Candida albicans</i> , <i>Fusarium moniliforme</i>	

**KEEP OUT OF REACH OF CHILDREN
DANGER:**

See Back Panel for Additional Precautions

10lbs Net Weight

Distributed by and manufactured for



Durvet Inc. Blue Springs, Missouri 64014-1-800-871-5570

Made in England by Antec International Limited

VirKon.S is a registered trademark of and manufactured by
Antec International Limited U.S. Patent No. 4,822,612

ACCEPTED

JUN 26 1996

Under the Federal Insecticide, Fungicide, and
Rodenticide Act, as amended, for the
pesticide registered under
EPA Reg. No.

62432-1

VirKon.S

DILUTION CHART

Quantity of Final Solution	1% Solution	2% Solution
Americas 1 gallon	1.3 ounces	2.7 ounces
10 gallons	13.4 ounces	26.7 ounces
50 gallons	66.8 ounces	133.5 ounces



1000 ml — 1000 ml
7.5 gallons



1000 ml — 1000 ml
15 gallons

For DISINFECTING use a rate of 7.5 gallons/1000 sq. ft.
For CLEANING AND DISINFECTING use a rate of 15 gallons/1000 sq. ft.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER

Powder is corrosive. Causes skin burns and irreversible eye damage. Harmful if swallowed, absorbed through skin, or inhaled. Do not get in eyes, on skin, or on clothing. Wear protective clothing and rubber gloves. Avoid breathing dust. Wear goggles, face shield, or safety glasses. Wash hands thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse. Corrosive substances return to powder only, not in use solution.

PRACTICAL TREATMENT

IF IN EYES: Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes. Get prompt medical attention.

IF ON SKIN: Wash with plenty of soap and water. Get medical attention if infection persists.

IF INHALED: If symptoms of coughing, choking, or wheezing are experienced, remove to fresh air and seek medical attention.

IF SWALLOWED: Drink plenty of water. Do not induce vomiting. Get prompt medical attention.

NOTICE OF PHYSICIAN: Possible mucousal damage may contraindicate the use of gastric lavage.



Manufactured for

Durvet Inc. Blue Springs, Missouri 64014-1-800-871-5570

Made in England by Antec International Limited

EPA Reg. No. 62432-1-12261. EPA Est. No. 62432-674-001

EQUINE BACTERIA

Clostridial diarrhea ✓
 Fistulous Withers (Poll Evil)
 Taylorella equigenitalis
 Streptococcus equi (Strangles)
 Pseudomonas mallei (Glanders) ✓
 Bordetella bronchiseptica

EQUINE VIRUSES

African Horse Sickness
 African Viral Arteritis (Pink Eye)
 Coital Exanthema
 Myeloencephalopathy
 Rhinopneumonitis

Equine Infectious Anemia (Swamp Fever)

Equine papillomatosis

Equine Contagious Abortion

Adenovirus Pneumonia

Equine Influenza (The Cough)

EQUINE FUNGI

Dermatophytosis (Ringworm)

Dermatophytosis (Mud Fever)

Fusarium moniliforme

BOVINE BACTERIA

Moraxella bovis

Mycobacterium bovis

Haemophilus somnus

BOVINE VIRUSES

Calf rotavirus

Infective Bovine Rhinotracheitis

Bovine Adenovirus Type 4

Pseudorabies

Foot & Mouth Disease

BOVINE FUNGI

Fusarium moniliforme

**Antec
International**

**V
(Virkon logo)**

**VIRKON® S
BROAD SPECTRUM DISINFECTANT**

**For Use in Cleaning and Disinfecting Industrial
Animal and Agricultural Facilities**

EFFECTIVE AGAINST:**BACTERIA**

Streptococcus pyogenes
 Campylobacter pyloridis
 Klebsiella pneumoniae
 Escherichia coli
 Salmonella typhimurium
 Salmonella choleraesuis
 Pseudomonas aeruginosa
 Staphylococcus aureus
 Staphylococcus epidermidis
 Mycoplasma gallisepticum
 Clostridium perfringens
 Bordetella avium

VIRUSES

Newcastle Disease
 Infectious Bronchitis
 Infectious Bursal Disease
 Avian Laryngotracheitis
 Avian Influenza
 Marek's Disease
 Egg Drop Syndrome
 Turkey Herpes Virus
 Duck Herpes Virus
 Duck Viral Enteritis

FUNGI

Aspergillus flavus
 Aspergillus fumigatus
 Candida albicans

SWINE BACTERIA

Bordetella bronchiseptica
 Pasteurella multocida
 Actinobacillus pleuropneumoniae
 Treponema hyodysenteriae
 Clostridium perfringens

SWINE VIRUSES

Hog Cholera
 Swine Influenza
 Porcine parvovirus
 Rotaviral diarrhea
 Vesicular stomatitis
 Pseudorabies
 Porcine Reproductive and
 Respiratory Syndrome (PRRS)
 African Swine Fever
 Foot and Mouth Disease

SWINE FUNGI

Fusarium moniliforme
**COMPANION ANIMALS
BACTERIA**

Streptococcus aureus
 Streptococcus pyogenes
 Klebsiella pneumoniae
 Pseudomonas aeruginosa

VIRUSES

Canine Parvovirus
 Distemper
 Leptospira canicola
 Feline parvovirus
 Feline herpes
 Feline calicivirus

FUNGI

Microsporium canis

ACTIVE INGREDIENTS

Potassium peroxymonosulfate..... 20.4%
 Sodium Chloride..... 1.5%
INERT INGREDIENTS..... 78.1%
TOTAL..... 100.0%

Equivalent to 9.75% Available Chlorine

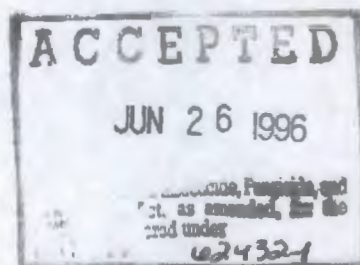
**KEEP OUT OF REACH OF CHILDREN
DANGER:**

See Back Panel for Additional Precautions

11 lbs (5Kg) Net Weight

ANTEC INTERNATIONAL LTD
 Windham Road, Chilton Industrial Estates }
 Sudbury Suffolk CO10 6XD, England.
 Tel: (1787) 77305 Telx: 987495 Fax: (1787) 310846

VIRKON S is a registered trademark of and manufactured by Antec International Limited



U.S. Patent No. 4822912

BROAD SPECTRUM DISINFECTANT

VIRKON S is effective against numerous microorganisms affecting animals: viruses, gram positive and gram negative bacteria, fungi (molds and yeasts), and mycoplasma. Efficacy was determined in the presence of hard water and organic material.

CONTROLS

Viruses of Newcastle Disease, Infectious Bronchitis, Infectious Bursal Disease, Avian Laryngotracheitis, Marek's Disease, Egg Drop Syndrome, Avian Influenza, Turkey Herpes Virus and Duck Viral Enteritis. **Fungi** (molds and yeasts - *Aspergillus flavus*, *Aspergillus fumigatus* and *Candida albicans*. **Bacteria** - *Streptococcus pyogenes*, *Campylobacter pyloridis*, *Klebsiella pneumoniae*, *Escherichia coli*, *Salmonella typhimurium*, *Salmonella choleraesuis*, *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Staphylococcus epidermidis*, *Bordetella avium* and *Mycoplasma gallisepticum*.

DIRECTIONS FOR USE

Federal law prohibits use of this product in a manner inconsistent with its labeling.

This powder formula is easily diluted for use in manual or machine operations.

POULTRY PRODUCTION/RATITE PRODUCTION

VIRKON S is recommended for use in hatcheries, chicken houses, Ratite production and processing plants.

HATCHERIES: **VIRKON S** at 1% solution is generally suitable for cleaning and disinfecting hatchers, setters, evaporative coolers, humidifying systems, ceiling fans, chicken houses, transfer trucks, trays, and plastic chick boxes (use 2% solution for *Mycoplasma*, *Aspergillus flavus* and *Aspergillus fumigatus*). **VIRKON S** is recommended for use in fogging (wet misting) operations as an adjunct either preceding or following regular cleaning and disinfecting procedures. **VIRKON S** at 1-2% solution is suitable. Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions.

BROILER/BREEDER HOUSES: Following removal of chickens, feed, and water troughs, remove manure and litter and spray floors and side walls with **VIRKON S** at 1% solution. Thoroughly wash waterers and feeders with a 1% solution of **VIRKON S** (use 2% solution for *Mycoplasma*, *Aspergillus flavus* and *Aspergillus fumigatus*). After contact for 10 minutes, rinse with potable water. Do not use to house poultry or employ equipment until treatment has dried.

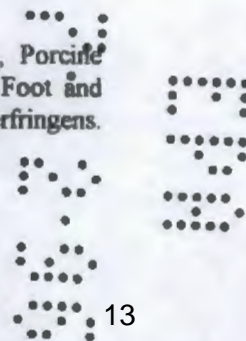
FOR AIR SANITIZING: Use **VIRKON S** at 1-2% solution. Fog the atmosphere until surfaces are moist. Allow at least 2 hours before entering area that has been fogged.

VIRKON S passes the AOAC germicidal and detergent sanitizer test at a concentration of 0.5% (1:200) in the presence of 200 ppm hard water.

PROCESSING PLANTS: For disinfecting and cleaning walls, ceilings, and floors spray at a dilution of 1%.

SWINE PRODUCTION

CONTROLS: Viruses of Hog Cholera, Swine influenza, Porcine Parvovirus, Pseudorabies, Porcine Reproductive and Respiratory Syndrome (PRRS) Rotoviral Diarrhea, African Swine Fever and Foot and Mouth Disease. Bacteria of *Pleuropneumonia*, *Treponema hyodysenteriae*, and *Clostridium perfringens*. Fungi: *Fusarium moniliforme*.



VIRKON S is recommended for use in farrowing pens, weaner accommodation, grower accommodation and finisher accommodation and processing plants. VIRKON S at 1% solution is generally suitable for cleansing and disinfecting (use 2% solution for *Mycoplasma*, *Aspergillus flavus* and *Aspergillus fumigatus*).

VIRKON S is recommended for use in fogging (wet misting) operations or as an adjunct either preceding or following regular cleaning and disinfecting procedures. VIRKON S at 1-2% solution is suitable. Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions.

EQUINE PRODUCTION

BROAD SPECTRUM EQUINE DISINFECTANT/DETERGENT/WASH

FOR CLEANING AND DISINFECTING STABLES, EQUIPMENT AND AERIAL DISINFECTION

APPLICATIONS

For cleaning and disinfection of all surfaces, equipment, utensils and instruments in Veterinary practices, kennels, stables, catteries, etc.

DIRECTIONS FOR USE

Add the contents of one VIRKON S sachet to one gallon of warm water. Solutions are stable for 7 days. Do not soak metal objects for long periods - 10 minutes is maximum necessary contact time. One gallon of solution is sufficient to treat 135 sq. ft.

For Topical Use On Animal: Shampoo infected area with VIRKON S using a clean sponge. Rinse with clean water. Apply three times a day Repeat as necessary. Stables, Horse Boxes, Tack Equipment and Feed-Rooms; Thoroughly dry clean. Then wash the area manually or with pressure washer with a 1% VIRKON S. Rinse with clean water. Blankets and Rugs; Shampoo by hand or spray lightly with a hand-sprayer and leave to dry. Shake or vacuum to remove residue. Aerial Spraying to control airborne diseases; By using a knapsack sprayer with fine setting or a VIRKON S SPRAY APPLICATION SYSTEM which automatically sprays the area. Spray for 2-3 minutes twice daily, first thing in the morning and last thing at night.

CONTROLS

Viruses of African Horse Sickness, Equine Viral Arteritis (Pink Eye), Coital Exanthema, Myeloencephalopathy, Rhinopneumonitis, Equine Contagious Abortion, Equine Papillomatosis, Equine Infectious Anemia (Swamp Fever), Adenovirus Pneumonia, Equine Influenza (The Cough) and Rhinitis, **Bacterial**; Clostridial Diarrhea, Fistulous Withers (Poll Evil), *Taylorella equigenitalis*, *Bordetella bronchiseptica*, *Streptococcus equi* (Strangles) and *Pseudomonas mallei* (Glanders). **Fungi**; Dermatophytosis (Ringworm), Dermatophytosis (Mud Fever), and *Fusarium moniliforme*.

BOVINE PRODUCTION

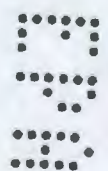
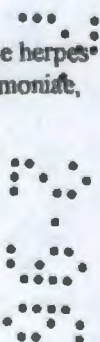
CONTROLS: **Viruses** of Calf rotavirus, Infectious Bovine Rhinotracheitis, Bovine Adenovirus Type 4 and Pseudorabies; **Bacteria** of *Moraxella bovis*, *Haemophilus somnus* and *Mycobacterium bovis*; **Fungi** of *Fusarium moniliforme*.

DIRECTIONS FOR USE

Virkon S is recommended for use in areas associated with bovine stabling, quarantine or feedlot facilities. Virkon S at 1% solution is generally suitable for cleansing and disinfection.

COMPANION ANIMALS

CONTROLS: **Viruses** Canine Parvovirus, Distemper, *Leptospira canicola*, Feline parvovirus, Feline herpes and Feline calicivirus. **Bacteria** of *Staphylococcus aureus*, *Streptococcus pyogenes*, *Klebsiella pneumoniae*, and *Pseudomonas aeruginosa*; **Fungi** of *Microsporum canis*.



COMPANION ANIMALS

APPLICATIONS:

Virkon S is recommended as a "one step" cleaning and disinfection procedure for all surfaces, equipment, instruments, utensils and caging systems associated with Veterinary Medical Hospitals, infectious disease wards, quarantine areas, Humane Society facilities, laboratory animal quarters, grooming and boarding facilities, kennels, catteries and animal transportation vehicles.

DIRECTIONS FOR USE:

Add the contents of one **Virkon S** sachet to one gallon of warm water. Solutions are stable for 7 days. Do not immerse metal objects in **Virkon S** for long periods - 10 minutes is maximum contact time.



**BACK PANEL
DILUTION CHART**

Quantity of Final Solution	1% Solution	2% Solution
American		
1 gallon	1.3 ounces	2.7 ounces
10 gallons	13.4 ounces	26.7 ounces
50 gallons	66.8 ounces	133.5 ounces
Metric		
10 liters	100 grams	200 grams
50 liters	500 grams	1000 grams
200 liters	2 kgs	4 kgs
125 g	6 oz	
100 g	5 oz	The measure cap holds when filled level 500 g or 17.5 ounces.
75 g	4 oz	
50 g	3 oz	
	2 oz	Brim full - contains 200 g or 17 ounces.
	1 oz	

**PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS
DANGER**

Powder is corrosive. Causes skin burns and irreversible eye damage. Harmful if swallowed, absorbed through skin, or inhaled. Do not get in eyes, on skin, or on clothing. Wear protective clothing and rubber gloves. Avoid breathing dust. Wear goggles, face shield, or safety glasses. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse. Corrosive statement refers to powder only **not** in use solution.

PRACTICAL TREATMENT

IF IN EYES: Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes. Get prompt medical attention.

IF ON SKIN: Wash with plenty of soap and water. Get medical attention if irritation persists.

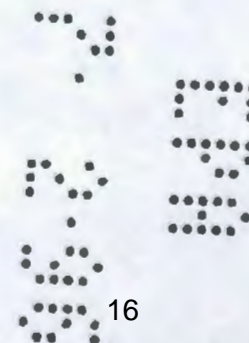
IF INHALED: or symptoms of coughing, choking, or wheezing are troublesome, remove to fresh air and seek medical attention.

IF SWALLOWED: Drink promptly a large quantity of water. Avoid alcohol. Get immediate medical attention.

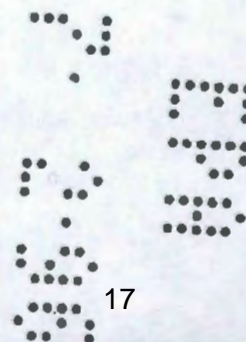
NOTICE OF PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

STORAGE AND DISPOSAL - Store in a cool, dry place in tightly closed container away from children. Always replace lid after use. Wash empty container thoroughly and dispose in trash. Do not mix this product with other chemicals.

ANTEC INTERNATIONAL LTD
Windham Road, Chilton Industrial Estates
Sudbury Suffolk CO10 6XD, England
Tel: (1787 77305 Telx: 987495 Fax: (1787) 310846



FIVE (5) COPIES OF REVISED LABELING



DR. ALAN R. WAGNER
Regulatory Affairs and Technical Services

Private Consultant
Clinical Investigations

2821 River Park Drive
Columbus, Ohio 43220

Ph: 614/459-5965
Fax: 614/459-9875

June 25, 1996

Document Processing Desk (AMENDMENT)
Mr. Robert Travaglini, PM 32 (H7505C)
Office of Pesticide Programs
401 M Street SW
Washington, DC 20460

Original
Copy

Re: Resubmittance of Revised VIRKON S (EPA No., 62432-1) Master Labeling
in Accordance With Letter of March 7, 1996 From Ms. Ruth Douglas

Dear Mr. Travaglini:

The enclosed three copies of the above described submission is being resubmitted to replace the copies that were hand delivered to the Document Desk on May 22, 1996 and stamped.

In accordance with your telephone request on June 25, 1996 these replace the copies that have not been located by your department.

If any further information is necessary, please contact me by phone or fax at the numbers indicated above.

Sincerely,

Alan R. Wagner
Alan R. Wagner, D.V.M., M.S.
Agent for Antec International Ltd.

ARW/mw

VIA CERTIFIED MAIL

18

DR. ALAN R. WAGNER
Regulatory Affairs and Technical Services

Private Consultant
Clinical Investigations

2821 River Park Drive
Columbus, Ohio 43220

Pfx 614/459-5965
Fac 614/459-8675

FACSIMILE TRANSMISSION

OUR FAX NUMBER 614/459-5965

TO:

Mr Robert Travaglini
EPA

FAX NO. CALLED:

703/305-5786

FROM:

Dr Alan R. Wagner

DATE:

6/25/96

NUMBER OF PAGES TO FOLLOW

1

PROBLEMS? CONTACT:

COMMENTS/SPECIAL INSTRUCTIONS:

*Copy of letter to Walter Francis
follows as per your telephone
request this date.*

Reviewer ID

TRANAGLINI

Submission No.

S 506112

Data Package No.

CODING FORM FOR APPLICATIONS FOR REGISTRATION/AMENDMENTS

File Symbol/Reg. No.

10 2432-1

PM

32

Action Code

301

|10| Descriptor (Amend/Resubmissions only)

|5| Intrastate Call-in ☐ (Y) Yes

|15| Child-resistant Packaging

☐ (C) Certification☐ (N) No☐ (S) Service Person

|20| Registration Type:

☐ (1) Conditional☐ (2) Unconditional☐ (R) Non-residential Use Only

|25| Proposed Classification: |30| Final Classification:

☐ (R) Restricted☐ (R) Restricted☐ (G) General☐ (N) Not Classified☐ (N) Not-Applicable

|35| Date on Application:

|04| EPA Received Date:

|40| Date Received by PM

MO	5	DAY	22	YR	96
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MO	5	DAY	22	YR	96
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MO	5	DAY	23	YR	96
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|80| Method of Support:

☐ (1) Cite-All☐ (6) Owner Submission☐ (4) Not Applicable☐ (7) Total Submission☐ (5) Not Submitted☐ (8) Selective Method

Reviewers Requested:

DATE
SENTDUE
DATEDATE
RETURNEDRESPONSE
CODERESPONSE
DATE

CH

EF

PL

DEB

NDEB

TB

EEB

EFGB

|115| FINAL Response
ACTION Code37

|120| Response

MO	6	DAY	26	YR	96
----	---	-----	----	----	----

75-DAY RESPONSE DUE DATE: ☐ (Y) Yes☐ (N) No

ALAN R. WAGNER
Regulatory Affairs and Technical Services

RECD EPA/OPP/DPD1

Private Consultant
Clinical Investigations

River Park Drive
Columbus, Ohio 43220

96 MAY 22 P3:24

Ph: 614/459-5965
Fax: 614/459-9875

May 22, 1996

Mr. Walter C. Francis
Acting Chief
Antimicrobial Branch (APB)
Registration Division (H7505C)
U.S. Environmental Protection Agency
Room 248, Crystal Mall II
1921 Jefferson Davis Highway
Arlington, VA. 22202

Re: Resubmittance of Revised VIRKON S (EPA No. 62432-1) Master Labeling
in Accordance With Letter of March 7, 1996 From Ms. Ruth Douglas

Dear Mr. Francis:

Pursuant to our meeting of May 2, 1996 and discussion/review of our VIRKON S labeling, please find attached the label revisions prepared in accordance with the letter of March 7th from Ms. Douglas and as you advised, for your review.

I do want to thank you for the opportunity to meet with you on May 2, 1996 and your excellent assistance and advice and the courtesy extended to me. Also, I appreciated being informed of the memorial service planned for Ms. Douglas and I will be in attendance.

I hope the resubmittance of the revised labeling will be acceptable and approved.

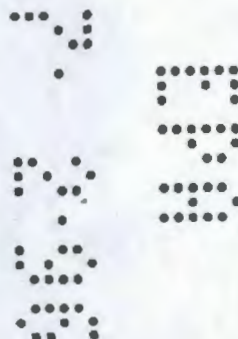
Sincerely,

Alan R. Wagner

Alan R. Wagner, D.V.M., M.S.
Agent for Antec International Ltd.

ARW/mw

VIA PERSONAL DELIVERY



(A) 	United States Environmental Protection Agency Office of Pesticide Programs (H7505C) Washington, DC 20460	<div style="border: 1px solid black; padding: 2px;"> <input type="checkbox"/> Registration <input type="checkbox"/> Amendment <input checked="" type="checkbox"/> Other </div>	OPP Identifier Number <div style="font-size: 24pt; font-weight: bold;">191006</div>
	Application for Pesticide:		

Section I

1. Company/Product Number 62432-1	2. EPA Product Manager Mr. Walter C. Francis	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) VIRKON S	PM# Acting Chief	
5. Name and Address of Applicant (Include ZIP Code) Antec International Ltd. Chilton Industrial Estate Sudbury, Suffolk CO10 6XD ENGLAND <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____

Section II

<input type="checkbox"/> Amendment - Explain below <input type="checkbox"/> Resubmission in response to Agency letter dated _____ <input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____ <input type="checkbox"/> "Me Too" Application. <input checked="" type="checkbox"/> Other - explain below.
--	--

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

1. Resubmission of revised labeling in accordance with Ms. Ruth Douglas' letter of March 7, 1996.
2. Five (5) copies of revised labeling.

Section III

1. Material This Product Will Be Packaged In:			
Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes," Unit Package wgt. _____ No. per container _____	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes," Package wgt. _____ No. per container _____	2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
* Certification must be submitted.			
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container	4. Size(s) of Retail Container 2.5 Kg, 5.0 Kg, 2.5 Kg 35 grams 50 grams		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product
6. Manner In Which Label Is Affixed To Product <input type="checkbox"/> Lithograph <input checked="" type="checkbox"/> Other (Pressure Sensitive) <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			

Section IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Alan R. Wagner, D.V.M., M.S.	Title Consultant, Regulatory Affairs Agent for Antec International	Telephone No. (Include Area Code) 614/459-5965
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature Alan R. Wagner, D.V.M., M.S.	3. Title Consultant, Regulatory Affairs Agent for Antec International Ltd.	
4. Typed Name Alan R. Wagner, D.V.M., M.S.	5. Date May 22, 1996	

DR. ALAN R. WAGNER
Regulatory Affairs and Technical Services

RECD EPA/OPP/DPQ1

Private Consultant
Clinical Investigations

2821 River Park Drive
Columbus, Ohio 43220

'96 MAY 22 P3:24

Ph: 614/459-5965
Fax: 614/459-9875

May 22, 1996

Mr. Walter C. Francis
Acting Chief
Antimicrobial Branch (APB)
Registration Division (H7505C)
U.S. Environmental Protection Agency
Room 248, Crystal Mall II
1921 Jefferson Davis Highway
Arlington, VA. 22202

Re: Resubmittance of Revised VIRKON S (EPA No. 62432-1) Master Labeling
in Accordance With Letter of March 7, 1996 From Ms. Ruth Douglas

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Pursuant to our meeting of May 2, 1996 and discussion/review of our VIRKON S labeling, please find attached the label revisions prepared in accordance with the letter of March 7th from Ms. Douglas and as you advised, for your review.

I do want to thank you for the opportunity to meet with you on May 2, 1996 and your excellent assistance and advise and the courtesy extended to me. Also, I appreciated being informed of the memorial service planned for Ms. Douglas and I will be in attendance.

I hope the resubmittance of the revised labeling will be acceptable and approved.

Sincerely,

Alan R. Wagner

Alan R. Wagner, D.V.M., M.S.
Agent for Antec International Ltd.

ARW/mw

VIA PERSONAL DELIVERY

(A) EPA		United States Environmental Protection Agency Office of Pesticide Programs (H7505C) Washington, DC 20460		<input type="checkbox"/> Registration <input type="checkbox"/> Amendment <input checked="" type="checkbox"/> Other	OPP Identifier Number 191006
		Application for Pesticide:			

Section I

1. Company/Product Number 62432-1	2. EPA Product Manager Mr. Walter C. Francis	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) VIRKON S	PM# Acting Chief	
5. Name and Address of Applicant (Include ZIP Code) Antec International Ltd. Chilton Industrial Estate Sudbury, Suffolk CO10 6XD ENGLAND <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____

Section II

<input type="checkbox"/> Amendment - Explain below <input type="checkbox"/> Resubmission in response to Agency letter dated _____ <input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____ <input type="checkbox"/> "Me Too" Application. <input checked="" type="checkbox"/> Other - explain below.
--	--

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

1. Resubmission of revised labeling in accordance with Ms. Ruth Douglas' letter of March 7, 1996.
2. Five (5) copies of revised labeling.

Section III

1. Material This Product Will Be Packaged in:			
Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
* Certification must be submitted.	If "Yes," Unit Package wgt. No. per container	If "Yes," Package wgt. No. per container	
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) of Retail Container 2.5 Kg, 5.0 Kg, 2.5 Kg 35 grams, 50 grams	
5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product		6. Manner In Which Label Is Affixed To Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled <input checked="" type="checkbox"/> Other (<u>Pressure Sensitive</u>)	

Section IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Alan R. Wagner, D.V.M., M.S.	Title Consultant, Regulatory Affairs Agent for Antec International	Telephone No. (Include Area Code) 614/459-5966

Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.	6. Date Application Received <div style="text-align: center;"> (Stamped) MAY 22 1996 PJ:25 </div>
2. Signature Alan R. Wagner, D.V.M., M.S.	3. Title Consultant, Regulatory Affairs Agent for Antec International Ltd
4. Typed Name Alan R. Wagner, D.V.M., M.S.	5. Date May 22, 1996

DR. ALAN R. WAGNER
Regulatory Affairs and Technical Services

Private Consultant
Clinical Investigations

2821 River Park Drive
Columbus, Ohio 43220

Ph: 614/459-5965
Fax: 614/459-9875

March 29, 1996

Ms. Ruth G. Douglas (PM32)
Antimicrobial Program Branch
Registration Division (H7505C)
U.S. Environmental Protection Agency
Room 278, Crystal Mall II
1921 Jefferson Davis Highway
Arlington, VA 22202

RE: VIRKON S
EPA Registration Number: 62432-1
Amendment Dated August 8, 1995
And Your Letter of Response Dated
March 7, 1996

Dear Ms. Douglas:

Thank you for your letter of March 7, 1996 in response to our amendment of revised master-labeling for **VIRKON S**. This label amendment superceded the ones dated April 11th and June 20th, 1995, as we agreed during our telephone conversation. I most certainly appreciated your assistance in this request.

I have reviewed and discussed with my client, Antec International, Ltd., your letter of March 7th, 1996 regarding your comments and unacceptability of the proposed labeling as submitted. Your letter proved most helpful in clarifying the issues in question as identified on the submitted labeling. We too had concerns that diseases rather than infectious organisms were present on previously approved labels.

Regarding our label claims for animal pathogens, these are zoonoses organisms, as you know, infecting both humans and animals and by default the reference refers to animal use only.

As a point of inquiry regarding the preparation of the resubmittance of an Application For Amendment in accordance with your letter of March 7, 1996, we would appreciate your review and guidance as to our proposals for acceptance and inclusion into our resubmitted Application For Amendment responding to the following points covered in your letter.

Comment # 1: "Delete *Campylobacter coli* and *Campylobacter jejuni*. These are also human pathogens. Data required." ----- We have enclosed data as requested. See Ref. No. 23.

Comment # 2: "Delete *Leptospirosis*." ----- We will delete on resubmission.

Comment # 3: "Delete *Salmonella enteritidis*. This is a human pathogen. Data Required." ----- We have enclosed data as requested. See Ref. No's. 28 & 70.

Comment # 4: "Delete Parainfluenza. This is a human pathogen. Data required." ----- We have enclosed data as requested. ----- See Ref. No. 71.

Comment # 5: "Delete Leukoencephalomalacia and Moldy Corn Poisoning. These are diseases." ----- These disease entities will be deleted from label resubmission since the etiological agent is *Fusarium moniliforme*. We have enclosed data for this organism. See Ref. No. 73.

Comment # 6: "Delete *Listeria monocytogenes*. This is a human pathogen. Data required." ----- We have enclosed data in reference to this organism being identified as a zoonotic disease. See Ref. No. 70.

Comment # 7: "Delete *Erysipelothrix rhusiopathiae*. This is a human pathogen. Data required." ----- We have enclosed data in reference to this organism being identified as a zoonotic disease. See Ref. No. 70.

Comment # 8: "Delete Bovine viral diarrhea. This is a disease." ----- This entity should be identified as BVD Pestivirus. We have enclosed data. See Ref. No. 71.

Comment # 9: "Delete Atrophic rhinitis, Colibacillosis, Enteritis, Mastitis, Necrotic Enteritis and Salmonellosis. These are diseases." ----- Atrophic rhinitis would be replaced by *Bordetella bronchiseptica* and *Pasteurella multocida*, both associated with this disease entity. We have enclosed data relating to this entity. See Ref. No's. 70 & 125.

Colibacillosis will be replaced with *E. coli*. Data is enclosed. See Ref. No. 109.

Enteritis, Mastitis, Necrotic Enteritis and Salmonellosis will be deleted from the resubmitted label.

Comment # 10: "Delete Transmissible Gastroenteritis. This is a disease." ----- This entity will be replaced by TGE coronavirus. We have enclosed data. See Ref. No. 71.

Comment # 11: "Delete Parainfluenza, Infectious hepatitis and Oral papillomatosis. These are diseases." ----- We would modify this entity as Parainfluenza virus, being a zoonotic organism to which several livestock species are susceptible.

Infectious hepatitis would be deleted and replaced by Infectious canine hepatitis (Adenovirus). We have enclosed data. See Ref. No. 49.

Oral papillomatosis would be replaced by Bovine papilloma virus. We have enclosed data for this entity. See No's. 2 & 110.

Comment # 12: "Delete Coronavirus. This is both a human and animal pathogen. Data are required." ----- This pathogen will be replaced on the label by TGE coronavirus and Infectious bronchitis virus. We have enclosed data as requested. See Ref. No's. 71 & 131 respectively.

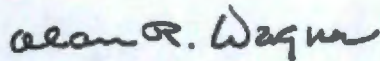
Comment #13: "Delete Rabies. This is a disease." ----- This entity will be deleted on resubmission.

Comment # 14 - 15: All references to use of VIRKON S in cleaning, sanitizing and disinfecting institutional and food processing and service facilities and references for use of product for the protection of hotel guests and ship passengers will be deleted in the preparation of the resubmittance of our Application For Amendment.

We are anxious to respond to your letter of March 7, 1996 and to amend our resubmission of VIRKON S Master Labeling in accordance with your comments and would appreciate your counsel and advice concerning our tentative responses to the comments defined in your letter.

Again, I want to thank you for the assistance and courtesy extended to me regarding our Regulatory Affairs concerns. I also hope, Ms. Douglas, that you have fully recovered from your illness and that I may have the opportunity to visit you in the near future. I would be most grateful for your advice and comments in reference to this submission.

Sincerely,



Alan R. Wagner, DVM., MS
Agent for Antec International Ltd.

ARW/mw

VIA CERTIFIED MAIL

cc: Francis Auchincloss
Antec International, Ltd.

Reviewer ID

Submission No.

Data Package No.

mclark

Douglas

5492359

CODING FORM FOR APPLICATIONS FOR REGISTRATION/AMENDMENTS

File Symbol/Reg. No. *62432-1* PM *32* Action Code *300*

☒ **10** Descriptor (Amend/Resubmissions only) *Amended labels*

☒ **5** Intrastate Call-in ☐ (Y) Yes ☐ (N) No ☒ **15** Child-resistant Packaging ☐ (C) Certification ☐ (S) Service Person

☒ **20** Registration Type: ☐ (R) Non-residential Use Only

☒ (1) Conditional ☐ (2) Unconditional

☒ **25** Proposed Classification: ☒ **30** Final Classification:

☐ (R) Restricted ☐ (R) Restricted ☐ (G) General ☐ (N) Not Classified

☒ **35** Date on Application: ☒ **04** EPA Received Date: ☒ **40** Date Received by PM

018/018/916 *018/110/915* *018/118/915*
MO DAY YR MO DAY YR MO DAY YR

☒ **80** Method of Support:

☐ (1) Cite-All ☐ (6) Owner Submission ☐ (4) Not Applicable ☐ (7) Total Submission ☐ (5) Not Submitted ☐ (8) Selective Method

Reviewers Requested:

CH
EF
PL
DEB
NDEB
TB
EEB
EFGB

DATE SENT	DUE DATE	DATE RETURNED	RESPONSE CODE	RESPONSE DATE

☒ **115** FINAL Response ACTION Code *12*

☐ **120** Response

MAR 7 1996

75-DAY RESPONSE DUE DATE: ☐ (Y) Yes ☐ (N) No

EPA

7-2-96

ACCEPTED

JUN 26 1996

Under the Federal Insecticide, Fungicide, and
Rodenticide Act, as amended, for
pesticide registered under
EPA Reg. No. 63432-1

BROAD SPECTRUM DISINFECTANT

VIRKON S is effective against numerous microorganisms affecting animals: viruses, Gram positive and Gram negative bacteria, fungi (molds and yeasts), and Mycoplasma. Efficacy was determined in the presence of hard water and organic material.

DIRECTION FOR USE

Federal law prohibits use of this product in a manner inconsistent with its labeling. This powder formula is easily diluted for use in manual or machine operations.

POULTRY PRODUCTION/RATITE PRODUCTION

VIRKON S is recommended for use in hatcheries, in chicken houses in Ratite production and processing plants.

CONTROLS: Bacteria of *Streptococcus pyogenes*, *Campylobacter pyloridis*, *Klebsiella pneumoniae*, *Escherichia coli*, *Salmonella typhimurium*, *Salmonella choleraesuis*, *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Staphylococcus epidermidis*, *Mycoplasma gallisepticum*, *Clostridium perfringens*, *Bordetella avium*. Viruses: Newcastle Disease, Infectious Bronchitis, Infectious Bursal disease, Avian Laryngotracheitis, Avian Influenza, Marek's Disease, Egg Drop Syndrome, Duck Viral Enteritis, Turkey Herpes Virus, African Swine Fever, Fungal, *Aspergillus flavus*, *Aspergillus fumigatus*, *Candida albicans*.

HATCHERIES: VIRKON S at 1% solution is generally suitable for cleaning and disinfecting hatcheries, setters, evaporative coolers, humidifying systems, ceiling fans, chicken houses, transfer trucks, trays, and plastic chick boxes (use 2% solution for *Mycoplasma* and *Aspergillus* flatus and 3% solution for *Aspergillus fumigatus*).

VIRKON S is recommended for use in logging (wet misting) operations as an adjunct either preceding or following regular cleaning and disinfecting procedures. VIRKON S at 1-2% solution is suitable. Fog (wet mist) until the area is moist using automatic wet foggers according to manufacturer's use directions.

BROILER/BREEDER HOUSES: Following removal of chickens, feed and water troughs remove manure and litter and spray floors and side walls with VIRKON S at 1%. Thoroughly wash waterers and feeders with a 1% solution of VIRKON S (use 2% solution for *Mycoplasma* and *Aspergillus* flatus and 3% solution for *Aspergillus fumigatus*). After contact for ten minutes, rinse with potable water. Do not use to house poultry or employ equipment until the treatment has dried.

SWINE PRODUCTION

CONTROLS: Bacteria of *Streptococcus pyogenes*, *Staphylococcus aureus*, *Klebsiella pneumoniae*, *Escherichia coli*, *Salmonella typhimurium*, *Salmonella choleraesuis*, *Pseudomonas aeruginosa*, *Staphylococcus epidermidis*, *Mycoplasma gallisepticum*, *Bordetella bronchiseptica*, *Pasteurella multocida*, *Campylobacter pyloridis*, *Clostridium perfringens*, *Actinobacillus pleuropneumoniae*, *Treponema hyodysenteriae*, *Bordetella avium*. Viruses: Hog cholera, Swine influenza, Porcine parvovirus, Rotaviral diarrhea, Vesicular stomatitis, Pseudorabies, PRRS (Porcine Reproductive & Respiratory Syndrome), African Swine Fever, Fungal, *Aspergillus flavus*, *Aspergillus fumigatus*, *Candida albicans*, *Fusarium moniliforme*.

VIRKON S is recommended for use in farrowing pens, weaner accommodation grower accommodation and finisher accommodation and processing plants. VIRKON S at 1% solution is generally suitable for cleaning and disinfecting (use 2% solution for *Mycoplasma* and *Aspergillus* flatus and 3% solution for *Aspergillus fumigatus*).

VIRKON S is recommended for use in logging (wet misting) operations or as an adjunct either preceding or following regular cleaning and disinfecting procedures. VIRKON S at 1-2% solution is suitable. Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions.

FOR AIR SANITIZING: Use VIRKON S at 1-2% solution. Fog the atmosphere until surfaces are moist. Allow at least 2 hours before entering area that has been fogged. VIRKON S passes the AOAC germicidal and detergent sanitizer test at a concentration of 0.5% (1:200) in the presence of 200 ppm hard water.

PROCESSING PLANTS: For disinfecting and cleaning walls, ceilings and floors, spray at a dilution of 1% (1:100).

STORAGE & DISPOSAL: Store in a cool, dry place in tightly closed container. Keep out of reach of children. Always replace lid after use. Wash empty container thoroughly and dispose of in trash.

durvet



VirKon® S

BROAD SPECTRUM DISINFECTANT

For Use in Cleaning and Disinfecting Industrial
Animal and Agricultural Facilities

EFFECTIVE AGAINST

BACTERIA	
<i>Streptococcus pyogenes</i> , <i>Campylobacter pyloridis</i> , <i>Klebsiella pneumoniae</i> , <i>Escherichia coli</i> , <i>Salmonella typhimurium</i> , <i>Salmonella choleraesuis</i> , <i>Pseudomonas aeruginosa</i> , <i>Staphylococcus aureus</i> , <i>Staphylococcus epidermidis</i> , <i>Mycoplasma gallisepticum</i> , <i>Clostridium perfringens</i> , <i>Bordetella avium</i> .	
VIRUSES OF	
Newcastle Disease, Infectious Bronchitis, Infectious Bursal disease, Avian Laryngotracheitis, Avian Influenza, Marek's Disease, Egg Drop Syndrome, Duck Viral Enteritis, Turkey Herpes Virus, African Swine Fever.	
FUNGI	
<i>Aspergillus flavus</i> , <i>Aspergillus fumigatus</i> , <i>Candida albicans</i> .	

ACTIVE INGREDIENTS

Potassium peroxymonosulfate 20.4%
Sodium Chloride 1.5%
INERT INGREDIENTS 78.1%
TOTAL 100.0%

Equivalent to 9.75% Available Chlorine

**KEEP OUT OF REACH OF CHILDREN
DANGER:**

See Back Panel for Additional Precautions

10lbs Net Weight

Distributed by and manufactured for

durvet

Durvet Inc. Blue Springs, Missouri, 64014-1-800-821-5570

Made in England by Antec International Limited

VIRKON S is a registered trademark of and manufactured by
Antec International Limited U.S. Patent No. 4822512



durvet



VirKon® S

BROAD SPECTRUM DISINFECTANT

For Use in Cleaning and Disinfecting Industrial
Animal and Agricultural Facilities

EFFECTIVE AGAINST

BACTERIA	
<i>Streptococcus pyogenes</i> , <i>Staphylococcus aureus</i> , <i>Klebsiella pneumoniae</i> , <i>Escherichia coli</i> , <i>Salmonella typhimurium</i> , <i>Salmonella choleraesuis</i> , <i>Pseudomonas aeruginosa</i> , <i>Staphylococcus epidermidis</i> , <i>Mycoplasma gallisepticum</i> , <i>Bordetella bronchiseptica</i> , <i>Pasteurella multocida</i> , <i>Campylobacter pyloridis</i> , <i>Clostridium perfringens</i> , <i>Actinobacillus pleuropneumoniae</i> , <i>Treponema hyodysenteriae</i> , <i>Bordetella avium</i> .	
VIRUSES OF	
Hog cholera, Swine influenza, Porcine parvovirus, Rotaviral diarrhea, Vesicular stomatitis, Pseudorabies, PRRS (Porcine Reproductive & Respiratory Syndrome), African Swine Fever.	
FUNGI	
<i>Aspergillus flavus</i> , <i>Aspergillus fumigatus</i> , <i>Candida albicans</i> , <i>Fusarium moniliforme</i> .	

**KEEP OUT OF REACH OF CHILDREN
DANGER:**

See Back Panel for Additional Precautions

10lbs Net Weight

Distributed by and manufactured for

durvet

Durvet Inc. Blue Springs, Missouri, 64014-1-800-821-5570

Made in England by Antec International Limited

VIRKON S is a registered trademark of and manufactured by
Antec International Limited U.S. Patent No. 4822512

VirKon® S

DILUTION CHART

Quantity of Final Solution	1% Solution	2% Solution
American 1 gallon	1.3 ounces	2.7 ounces
10 gallons	13.4 ounces	26.7 ounces
50 gallons	66.8 ounces	133.5 ounces



For DISINFECTING use a rate of 7.5 gallons/1000 sq. ft.
For CLEANING AND DISINFECTING use a rate of 15 gallons/1000 sq. ft.

PRECAUTIONARY STATEMENTS

**HAZARDS TO HUMANS AND
DOMESTIC ANIMALS**

DANGER

Powder is corrosive. Causes skin burns and irreversible eye damage. Harmful if swallowed, absorbed through skin, or inhaled. Do not get in eyes, on skin, or on clothing. Wear protective clothing and rubber gloves. Avoid breathing dust. Wear goggles, face shield, or safety glasses. Wash hands thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse. Corrosive statement refers to powder only, not in use solution.

PRACTICAL TREATMENT

IF IN EYES: Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes. Get prompt medical attention.

IF ON SKIN: Wash with plenty of soap and water. Get medical attention if irritation persists.

IF INHALED: or symptoms of coughing, choking, or wheezing are troublesome, remove to fresh air and seek medical attention.

IF SWALLOWED: Drink promptly a large quantity of water. Avoid alcohol. Get immediate medical attention.

NOTICE OF PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

durvet

Manufactured for

Durvet Inc. Blue Springs, Missouri, 64014-1-800-821-5570

Made in England by Antec International Limited

EPA Reg. No. 62432-1-12281. EPA Est. No. 62432-EN-001

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

MAR 7 1996

Dr. Alan R. Wagner, D.V.M., M.S.
Agent for Antec International Limited
Chilton Industrial Estate
Sudbury Suffolk CO10 6XD
England

Dear Dr. Wagner:

Subject: Virkon S
EPA Registration No. 62432-1
Your Amendment Dated August 8, 1995

This is in response to your amendment of revised master labeling for the subject product. Per our telephone conversation, this label amendment submission supercedes the ones dated April 11th and June 20th 1995.

The submitted labeling is not acceptable. It must be revised in accordance with the following comments and resubmitted for our review.

1. Delete *Campylobacter coli* and *Campylobacter jejuni*. These are also human pathogens. Therefore, data are required.
2. Delete Leptospirosis. This is the disease.
3. Delete "Salmonella enteritidis". This is a human pathogen. Data are required.
4. Delete "Parainfluenza". This is a human pathogen. Data are required.
5. Delete "Leukoencephalomalacia" and "Moldy corn poisoning". These are diseases.
6. Delete "*Listeria monocytogenes*". This is a human pathogen. Data are required.
7. Delete "*Erysipelothrix rhusiopathiae*". This a human pathogen. Data are required.
8. Delete "Bovine viral diarrhea. This is a disease.

CONCURRENCES

SYMBOL								
SURNAME								
DATE								

9. Delete "Atrophic Rhinitis, Colibacillosis, Enteritis, Mastitis, Necrotic Enteritis and Salmonellosis. These are diseases.
10. Delete "Transmissible Gastroenteritis". This is a disease.
11. Delete "Parainfluenza, Infectious hepatitis and Oral papillomatosis". These are diseases.
12. Delete "Coronavirus. This is both a human and animal pathogen. Data are required.
13. Delete rabies. This is the disease.

All of the above pathogens and diseases must be deleted wherever they appear throughout the labeling.

14. This product has only been accepted for use in Cleaning and Disinfecting Industrial Animal and Agricultural Facilities.

Delete all references (delete p. 4) to use of this product in cleaning, sanitizing and disinfecting institutional and food processing and service facilities. Efficacy data are required to support these uses. Also, the formulation must be cleared for use on food contact surfaces.

15. Delete all references (delete p. 5) to use of this product for the protection of hotel guests and ship passengers (virucide, bactericide, fungicide). No data has been submitted to support any of these claims.

Submit five (5) copies of revised labeling for our review.

If you have any questions concerning this letter, please call me at (703) 305-7964.

Sincerely yours,



Ruth Douglas
Product Manager (32)
Antimicrobial Program Branch
Registration Division (7505C)

EQUINE BACTERIA
 Clostridial diarrhea
 Enteric Colibacillosis
 Fistulous Withers (Poll Evil)
 Taylorella equigenitalis
 Streptococcus equi (Strangles)
 Pseudomonas mallei (Glanders)
 Bordetella bronchiseptica
 Salmonella enteritidis

EQUINE VIRUSES
 African Horse Sickness
 Equine Viral Arteritis (Pink Eye)
 Coital Exanthema
 Myeloencephalopathy
 Rhinopneumonitis
 Equine Infectious Anemia (Swamp Fever)
 Equine papillomatosis
 Equine Contagious Abortion
 Adenovirus Pneumonia
 Equine Influenza (The Cough)
 Parainfluenza

EQUINE FUNGI
 Dermatophytosis (Ringworm)
 Dermatomyiasis (Mud Fever)
 Fusarium moniliforme
 Leukoencephalomalacia
 Moldy Corn Poisoning

BOVINE BACTERIA
 Listeria monocytogenes
 Moraxella bovis
 Erysipelothrix rhusiopathiae
 Mycobacterium bovis
 Haemophilus somnus
BOVINE VIRUSES
 Calf rotavirus
 Infective Bovine Rhinotracheitis
 Bovine Viral Diarrhea
 Rabies
 Bovine Adenovirus Type 4
 Pseudorabies
 Foot & Mouth Disease
BOVINE FUNGI
 Fusarium moniliforme

Antec
International
V
(Virkon logo)

VIRKON® S
BROAD SPECTRUM DISINFECTANT

For Use In Cleaning and Disinfecting Industrial
 Animal and Agricultural Facilities

EFFECTIVE AGAINST:

BACTERIA	VIRUSES	FUNGI
Streptococcus pyogenes	Newcastle Disease	Aspergillus flavus
Campylobacter pyloridis	Infectious Bronchitis	Aspergillus fumigatus
Klebsiella pneumoniae	Infectious Bursal Disease	Candida albicans
Escherichia coli	Avian Laryngotracheitis	
Salmonella typhimurium	Avian Influenza	
Salmonella choleraesuis	Marek's Disease	
Salmonella enteritidis	Egg Drop Syndrome	
Pseudomonas aeruginosa	Turkey Herpes Virus	
Staphylococcus aureus	Duck Herpes Virus	
Staphylococcus epidermidis	Duck Viral Enteritis	
Mycoplasma gallisepticum		
Clostridium perfringens		
Bordetella avium		

ACTIVE INGREDIENTS
 Potassium peroxydimesulfate..... 20.4%
 Sodium Chloride..... 1.5%
INERT INGREDIENTS..... 78.1%
TOTAL.....100.0%

Equivalent to 9.75% Available Chlorine

KEEP OUT OF REACH OF CHILDREN
DANGER:

See Back Panel for Additional Precautions

11 lbs (5Kg) Net Weight

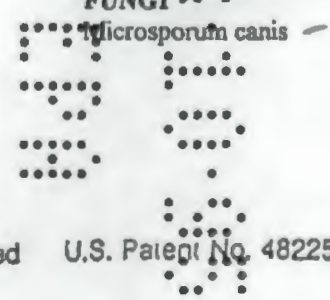
ANTEC INTERNATIONAL LTD
 Windham Road, Chilton Industrial Estates
 Sudbury Suffolk CO10 6XD, England
 Tel: (1787) 77305 Telx: 987495 Fax: (1787) 310846

SWINE BACTERIA
 Bordetella bronchiseptica
 Pasteurella multocida
 Campylobacter coli
 Campylobacter jejuni
 Atrophic Rhinitis
 Colibacillosis
 Enteritis
 Mastitis
 Necrotic Enteritis
 Salmonellosis
 Erysipelothrix rhusiopathiae
 Leptospirosis
 Actinobacillus pleuropneumoniae
 Treponema hyodysenteriae
 Listeria monocytogenes
 Clostridium perfringens

SWINE VIRUSES
 Hog Cholera
 Swine Influenza
 Transmissible Gastroenteritis
 Porcine parvovirus
 Rotaviral diarrhea
 Vesicular stomatitis
 Pseudorabies
 Porcine Reproductive and
 Respiratory Syndrome (PRRS)
 African Swine Fever
 Foot and Mouth Disease
 Rabies

SWINE FUNGI
 Fusarium moniliforme

COMPANION ANIMALS
BACTERIA
 Staphylococcus aureus
 Streptococcus pyogenes
 Klebsiella pneumoniae
 Pseudomonas aeruginosa
VIRUSES
 Canine Parvovirus
 Distemper
 Rabies
 Parainfluenza
 Infectious hepatitis
 Oral papillomatosis
 Coronavirus
 Leptospira canicola
 Feline parvovirus
 Feline herpes
 Feline calicivirus
FUNGI
 Microsporium canis



VIRKON S is a registered trademark of and manufactured by Antec International Limited U.S. Patent No. 4822512

BROAD SPECTRUM DISINFECTANT

VIRKON S is effective against numerous microorganisms affecting animals: viruses, gram positive and gram negative bacteria, fungi (molds and yeasts), and mycoplasma. Efficacy was determined in the presence of hard water and organic material.

CONTROLS

Viruses of Newcastle Disease, Infectious Bronchitis, Infectious Bursal Disease, Avian Laryngotracheitis, Marek's Disease, Egg Drop Syndrome, Avian Influenza, Turkey Herpes Virus and Duck Viral Enteritis. **Fungi** (molds and yeasts - *Aspergillus flavus*, *Aspergillus fumigatus* and *Candida albicans*. **Bacteria** - *Streptococcus pyogenes*, *Campylobacter pyloridis*, *Klebsiella pneumoniae*, *Escherichia coli*, *Salmonella typhimurium*, *Salmonella choleraesuis*, *Salmonella enteritidis*, *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Staphylococcus epidermidis*, *Bordetella avium*, *Mycoplasma gallisepticum* and *Necrotic Enteritis*.

DIRECTIONS FOR USE

Federal law prohibits use of this product in a manner inconsistent with its labeling.

This powder formula is easily diluted for use in manual or machine operations.

POULTRY PRODUCTION/RATITE PRODUCTION

VIRKON S is recommended for use in hatcheries, chicken houses, Ratite production and processing plants.

HATCHERIES: VIRKON S at 1% solution is generally suitable for cleaning and disinfecting hatcheries, setters, evaporative coolers, humidifying systems, ceiling fans, chicken houses, transfer trucks, trays, and plastic chick boxes (use 2% solution for *Mycoplasma*, *Aspergillus flavus* and *Aspergillus fumigatus*). VIRKON S is recommended for use in fogging (wet misting) operations as an adjunct either preceding or following regular cleaning and disinfecting procedures. VIRKON S at 1-2% solution is suitable. Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions.

BROILER/BREEDER HOUSES: Following removal of chickens, feed, and water troughs, remove manure and litter and spray floors and side walls with VIRKON S at 1% solution. Thoroughly wash waterers and feeders with a 1% solution of VIRKON S (use 2% solution for *Mycoplasma*, *Aspergillus flavus* and *Aspergillus fumigatus*). After contact for 10 minutes, rinse with potable water. Do not use to house poultry or employ equipment until treatment has dried.

FOR AIR SANITIZING: Use VIRKON S at 1-2% solution. Fog the atmosphere until surfaces are moist. Allow at least 2 hours before entering area that has been fogged.

VIRKON S passes the AOAC germicidal and detergent sanitizer test at a concentration of 0.5% (1:200) in the presence of 200 ppm hard water.

PROCESSING PLANTS: For disinfecting and cleaning walls, ceilings, and floors spray at a dilution of 1%.

SWINE PRODUCTION

CONTROLS: Viruses of Hog Cholera, Swine influenza, Transmissible Gastroenteritis, Porcine Parvovirus, Vesicular Stomatitis, Pseudorabies, Porcine Reproductive and Respiratory Syndrome (PRRS), Rotoviral Diarrhea, African Swine Fever, Foot and Mouth Disease and Rabies. Bacteria of *Atrophic Rhinitis*, *Colibacillosis*, *Leptospirosis*, *Mastitis*, *Necrotic Enteritis*, *Pleuropneumonia*, *Salmonellosis*, *Treponema hyodysenteriae*, *Listeria monocytogenes* and *Clostridium perfringens*. Fungi: *Fusarium moniliforme*.

VIRKON S is recommended for use in farrowing pens, weaner accommodation, grower accommodation and finisher accommodation and processing plants: VIRKON S at 1% solution is generally suitable for cleansing and disinfecting (use 2% solution for Mycoplasma, Aspergillus flavus and Aspergillus fumigatus).

VIRKON S is recommended for use in fogging (wet misting) operations or as an adjunct either preceding or following regular cleaning and disinfecting procedures. VIRKON S at 1-2% solution is suitable. Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions.

EQUINE PRODUCTION

BROAD SPECTRUM EQUINE DISINFECTANT/DETERGENT/WASH

FOR CLEANING AND DISINFECTING STABLES, EQUIPMENT AND AERIAL DISINFECTION

APPLICATIONS

For cleaning and disinfection of all surfaces, equipment, utensils and instruments in Veterinary practices, kennels, stables, catteries, etc.

DIRECTIONS FOR USE

Add the contents of one VIRKON S sachet to one gallon of warm water. Solutions are stable for 7 days. Do not soak metal objects for long periods - 10 minutes is maximum necessary contact time. One gallon of solution is sufficient to treat 135 sq. ft.

For Topical Use On Animal; Shampoo infected area with VIRKON S using a clean sponge. Rinse with clean water. Apply three times a day Repeat as necessary. Stables, Horse Boxes, Feed Rooms; Thoroughly dry clean. Then wash the area manually or with pressure washer with a 1% VIRKON S. Rinse with clean water. Blankets and Rugs; Shampoo by hand or spray lightly with a hand-sprayer and leave to dry. Shake or vacuum to remove residue. Aerial Spraying to control airborne diseases; By using a knapsack sprayer with fine setting or a VIRKON S SPRAY APPLICATION SYSTEM which automatically sprays the area. Spray for 2-3 minutes twice daily, first thing in the morning and last thing at night.

CONTROLS

Viruses of African Horse Sickness, Equine Viral Arteritis (Pink Eye), Coital Exanthema, Myeloencephalopathy, Rhinopneumonitis, Equine Contagious Abortion, Equine Papillomatosis, Equine Infectious Anemia (Swamp Fever), Adenovirus Pneumonia, Parainfluenza, Equine Influenza (The Cough) and Rhinitis, Bacterial; Clostridial Diarrhea, Salmonella enteritidis, Enteric Colibacillosis, Fistulous Withers (Poll Evil), Taylorella equigenitalis, Bordetella bronchiseptica, Streptococcus equi (Strangles) and Pseudomonas mallei (Glanders). Fungi; Dermatophytosis (Ringworm), Dermatophytosis (Mud Fever), Fusarium moniliforme, Leukoencephalomalacia, and Moldy corn poisoning.

BOVINE PRODUCTION

CONTROLS: Viruses of Calf rotavirus, Infectious Bovine Rhinotracheitis, Bovine Viral Diarrhea, Rabies, Bovine Adenovirus Type 4 and Pseudorabies; Bacteria of Listeria monocytogenes, Moraxella bovis, Erysipelothrix rhusiopathiae, Haemophilus somnus and Mycobacterium bovis; Fungi of Fusarium moniliforme.

DIRECTIONS FOR USE

Virkon S is recommended for use in areas associated with bovine stabling, quarantine or feedlot facilities. Virkon S at 1% solution is generally suitable for cleansing and disinfection.

COMPANION ANIMALS

CONTROLS: Viruses of Canine Parvovirus, Distemper, Rabies, Parainfluenza, Infectious hepatitis, Oral papillomatosis, Coronavirus, Leptospira canicola, Feline parvovirus, Feline herpes and Feline calicivirus. Bacteria of Staphylococcus aureus, Streptococcus pyogenes, Klebsiella pneumoniae, and Pseudomonas aeruginosa; Fungi of Microsporum canis.

FOR CLEANING, SANITIZING AND DISINFECTING INSTITUTIONAL AND FOOD PROCESSING AND SERVICE FACILITIES

Virkon S is recommended for use in food handling and food preparation areas of restaurants and food processing plants, and in: stores, factories, schools, hotels, offices, ships, planes, transportation terminals, supermarkets and food warehouses.

Virkon S is effective against wide range of viruses, bacteria and fungi including *Streptococcus pyogenes*, *Campylobacter pyloridis*, *Klebsiella pneumonia*, *Escherichia coli*, *Salmonella typhimurium*, *Salmonella choleraesuis*, *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Staphylococcus epidermidis*, *Mycoplasma gallisepticum*, *Salmonella enteritidis*, *Listeria monocytogenes*, *Clostridium perfringens*, *Shigella sonnei*, *Aspergillus flavus*, *Candida albicans* and *Aspergillus fumigatus*.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Virkon S passes the AOAC Germicidal and Detergent sanitizer tests at a concentration of 0.5% (1:200).


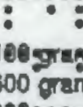
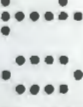
With Virkon S, only one product is needed to clean and sanitize or disinfect all surfaces.

Cleaning and Sanitizing Food Contact Surfaces. Remove gross dirt and wash surface with a 0.5% Virkon S solution prepared according to the table below. Apply to surface using a sponge, brush, or spray device until the surface is visibly clean. For non-porous surfaces, rinse and apply 0.2% solution to surface. Let stand 2 minutes and rinse with potable water. For porous surfaces, rinse and apply 0.6% solution to surface. Let stand 2 minutes and rinse with potable water.

Cleaning and Disinfecting Non-food Contact Surfaces. Remove gross dirt and prepare 1.0% Virkon S solution prepared according to the table below. Apply to surface using a mop sponge, brush, or spray device until the surface is visibly clean. Air dry. In cases of fungal or viral contamination of non-food contact surfaces, follow these instructions substituting a 2.0% Virkon S solution.

Sanitizing Toilet Bowls. After flushing, sprinkle Virkon S powder around the bowl, scrub with a brush, leave for 10 minutes. Flush.

DILUTION CHART

To this much water:	0.2% solution add this much VIRKON S (200ppm available Chlorine)	0.5% solution add this much VIRKON S (500ppm available Chlorine)	0.6% solution add this much VIRKON S (600ppm available Chlorine)	1% solution add this much VIRKON S (1000ppm available Chlorine)	2% solution add this much VIRKON S (2000ppm available Chlorine)
American 1 gallon 10 gallons 50 gallons	0.3 ounces 2.6 ounces 13.4 ounces	0.7 ounces 6.7 ounces 33.4 ounces	0.9 ounces 7.8 ounces 40.2 ounces	1.3 ounces 13.4 ounces 66.8 ounces	 2.6 ounces 26.4 ounces 133.6 ounces
Metric 10 litres 50 litres 200 litres	20 grams 125 grams 500 grams	50 grams 250 grams 1000 grams	60 grams 300 grams 1200 grams	 100 grams 500 grams 2000 grams	 200 grams 1000 grams 4000 grams

VIRKON S FOR THE PROTECTION OF HOTEL GUESTS AND SHIP PASSENGERS

VIRUCIDE, BACTERICIDE, FUNGICIDE

INFECTIOUS SOURCE	THE DANGERS	CONTROL	VIRKON S
PEOPLE - from saliva.	Transmits bacteria and viruses including staphylococci and streptococci and herpes virus.	Clean and sanitize all crockery, cutlery and drinking glasses with Virkon S solution. Also containers in which crockery etc is transported. Change frequently.	Use 0.5% Virkon S to clean and sanitize. Rinse in water.
PEOPLE - from poor personal hygiene and from surfaces in toilets, wash basins, etc.	Transmits bacteria and viruses causing enteritis, dysentery and typhoid.	Clean and disinfect all surfaces in the bathroom twice daily with Virkon S.	Use 1.0% Virkon S to clean and disinfect. Rinse in water.
PEOPLE - fungal foot infections.	Athletes foot infections in swimming pool changing areas, bathroom floors.	Clean and disinfect floors daily with Virkon S.	Use 1.0% Virkon S to clean and disinfect.
PEOPLE - Nursery play areas	From young children where personal hygiene is poor - contaminating equipment and play areas.	Clean and disinfect play areas and equipment twice daily with Virkon S.	Use 1.0% Virkon S to clean and disinfect. Rinse in water.
PEOPLE - Blood, body fluids, vomit.	All blood should be treated as HIV positive; vomit and body fluids are also highly infective.	Cover heavy blood spillage with Virkon S powder. Leave for 10 minutes, then scoop into plastic bag.	Use 1.0% Virkon S to clean and disinfect area.
FOOD PREPARATION AREA - from Poultry, Meat, Fish, Cheese	From contamination by Salmonella, Listeria monocytogenes, Escherichia coli, Shigella sonnei, Campylobacter	Clean and sanitize all surfaces and equipment on which food is prepared with Virkon S 3 or 4 times daily. Clean and sanitize cheese boards, containers regularly.	Use 0.5% Virkon S to clean. Rinse. Apply 0.2% solution and let stand 2 minutes. Rinse with potable water.
VEGETABLE PREPARATION AREA	From vegetables contaminated with soil containing organisms of human and animal fecal origin.	Clean and sanitize all surfaces in this area - including sinks, work benches, floors, containers in which vegetables pass to kitchen.	Use 0.5% Virkon S to clean. Rinse. Apply 0.2% solution and let stand 2 minutes. Rinse with potable water.
FOOD - Preparation in the kitchen	Infection from all surfaces: benches, mixing bowls, equipment used for preparing cold items, cream, mayonnaise and cutting meat for cold buffet etc. Contamination as above.	Clean and sanitize with Virkon S solution regularly - several times daily and between different foods.	Use 0.5% Virkon S to clean. Rinse. Apply 0.2% solution and let stand 2 minutes. Rinse with potable water.
WASTE FOOD BINS	Contamination as above.	Clean and disinfect daily with Virkon S solution.	Use 1.0% Virkon S to clean and disinfect. Rinse in water.
BARS/RESTAURANTS - Crockery, cutlery, drinking glasses in restaurants and bars and in the trays in which they are transported.	From people who transmit viral and bacterial contaminants from saliva and hands.	Clean and sanitize. Wash all glasses etc in Virkon S solution.	Use 0.5% Virkon S to clean and sanitize. Rinse in water. Change Virkon S solution frequently.

N.B. Where dishwashing/pot washing machines are available, if properly operated, the items should be sterile when they leave this machine. At this stage they are open to contamination from people and surfaces; for this reason all surfaces and equipment in the known food processing zone should be washed with Virkon S. This single operation will clean and sanitize thus preventing the spread of infection and contamination which occurs when cleaning is done using a detergent only.

**BACK PANEL
DILUTION CHART**

Quantity of Final Solution	1% Solution	2% Solution
American		
1 gallon	1.3 ounces	2.7 ounces
10 gallons	13.4 ounces	26.7 ounces
50 gallons	66.8 ounces	133.5 ounces
Metric		
10 liters	100 grams	200 grams
50 liters	500 grams	1000 grams
200 liters	2 kgs	4 kgs
125 g	6 oz	
100 g	5 oz	The measure cap holds when filled
75 g	4 oz	level 500 g or 17.5 ounces.
50 g	3 oz	
	2 oz	Brim full - contains 200 g or 17 ounces.
	1 oz	

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER

Powder is corrosive. Causes skin burns and irreversible eye damage. Harmful if swallowed, absorbed through skin, or inhaled. Do not get in eyes, on skin, or on clothing. Wear protective clothing and rubber gloves. Avoid breathing dust. Wear goggles, face shield, or safety glasses. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse. Corrosive statement refers to powder only **not** in use solution.

PRACTICAL TREATMENT

IF IN EYES: Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes. Get prompt medical attention.

IF ON SKIN: Wash with plenty of soap and water. Get medical attention if irritation persists.

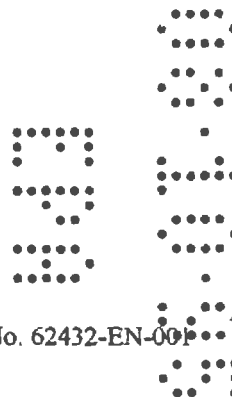
IF INHALED: or symptoms of coughing, choking, or wheezing are troublesome, remove to fresh air and seek medical attention.

IF SWALLOWED: Drink promptly a large quantity of water. Avoid alcohol. Get immediate medical attention.

NOTICE OF PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

STORAGE AND DISPOSAL - Store in a cool, dry place in tightly closed container away from children. Always replace lid after use. Wash empty container thoroughly and dispose in in trash. Do not mix this product with other chemicals.

ANTEC INTERNATIONAL LTD
Windham Road, Chilton Industrial Estates
Sudbury Suffolk CO10 6XD, England
Tel: (1787 77305 Telx: 987495 Fax: (1787) 310846



8-10-95
OJEP# 228184

FRONT END PROCESSING APPLICATION INFORMATION CHECK

PM 38

EPA COMPANY NUMBER 62432-1

EPA REGISTRATION NUMBER
STATUS (For Amendments)

Active ☒ Cancelled ☐

Not in REFS ☐

"ME-TOO" CITED PRODUCT STATUS

Active ☐ Cancelled ☐

Not in REFS ☐

PRAT RECORD CREATED ☐

AMENDMENT

app# 228184

FAST TRACK * APPLICATION FOR AMENDMENT

WITH DATA

Init. Date

FEU

SIG (DATA)

FEU

PM

NO DATA

Init. Date

FEU

32
PM

Jan 8-10-95

REGULAR APPLICATION FOR AMENDMENT

WITH DATA

Init. Date

FEU

SIG (DATA)

PM

NO DATA

Init. Date

FEU

PM

- * Front End Processing determined this application qualifies for fast track review based on registrants claim of "no-too". No screen for substantial similarity is made by the Front End.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

08/10/95

ALAN WAGNER
DR ALAN WAGNER, DVM, MS
2304 ANHINGA DR
KISSIMMEE FL 34743

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

PRODUCT NAME: VIRKON S
COMPANY NAME: DR ALAN WAGNER, DVM, MS
OPP IDENTIFICATION NUMBER: 228184
EPA REGISTRATION NUMBER: 62432-1
EPA RECEIPT DATE: 08/10/95

SUBJECT: RECEIPT OF AMENDMENT

DEAR REGISTRANT:

The Office of Pesticide Programs has received your application for an amendment and it has passed an administrative screen for completeness.

During the initial screen we determined that the application qualifies for fast track review. The package will now be forwarded to the Product Manager for review to determine its acceptability.

If you have any questions, please contact Ruth Douglas, Product Manager 32, at (703)-305-7964.

Sincerely,

A. Wrice

Front End Processing Staff
Information Services Branch
Program Management and Support Division

A

DR. ALAN R. WAGNER
Regulatory Affairs and Technical Services

B

Private Consultant
Clinical Investigations

2304 Anhinga Drive
Kissimmee, Florida 34743

Ph: 407/344-9803
Fax: 407/344-9980

August 8, 1995

Ms. Ruth G. Douglas (PM32)
Antimicrobial Program Branch
Registration Division (7505C)
U.S. Environmental Protection Agency
Room 278 Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, Virginia 22202

Subject: VIRKON S (EPA Reg. # 62432-1)
Master Label Update

Dear Ms. Douglas:

Please find enclosed for your review "Application For Pesticide Amendment" updating our EPA Master Label for VIRKON S.

In reference to the previous Master Label Amendment submitted to you on June 20, 1995, I would appreciate your review of the enclosed amendment update, Ms. Douglas, which I hope can be attached to the June 20, 1995 submission so as to expedite the review and approval process.

The enclosed Master Label Amendment concerns an updated section identifying the use of VIRKON S for cleaning, sanitizing and disinfecting institutional and food processing and service facilities.

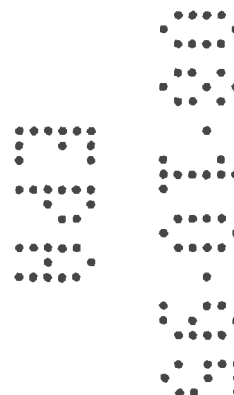
I do want to thank you for your excellent cooperation, assistance and courtesy extended to me by you and your staff regarding our EPA regulatory affairs activities. Looking forward to seeing you again soon.

Sincerely,

Alan R. Wagner
Alan R. Wagner, D.V.M., M.S.
Agent for Antec International Ltd.

ARW/mw

Enclosures



Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060, Approval expires 11-30-93

(A)		United States Environmental Protection Agency Office of Pesticide Programs (H7505C) Washington, DC 20460 Application for Pesticide:	<input type="checkbox"/> Registration <input checked="" type="checkbox"/> Amendment <input type="checkbox"/> Other	OPP Identifier Number
			191012 228184	

Section I

1. Company/Product Number 62432-1	2. EPA Product Manager Ms. Ruth G. Douglas	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) VIRKON S	PM# 32	
5. Name and Address of Applicant (Include ZIP Code) Antec International Ltd. Chilton Industrial Estates Sudbury, Suffolk C0106XD ENGLAND <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____

Section II

<input checked="" type="checkbox"/> Amendment - Explain below <input type="checkbox"/> Resubmission in response to Agency letter dated _____ <input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____ <input type="checkbox"/> "Me Too" Application. <input type="checkbox"/> Other - explain below.
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Explanation: Use additional page(s) if necessary. (For section I and Section II.)

1. Submission of amendment for Master Label Update
2. Five (5) copies of amended Master Label

Section III

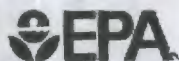
1. Material This Product Will Be Packaged In:			
Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
* Certification must be submitted.		If "Yes," Unit Package wgt. No. per container	If "Yes," Package wgt. No. per container
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) of Retail Container 2.5 Kg, 5.0 Kg, 2.5 Kg 35 grams, 50 grams	
		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label Is Affixed To Product <input type="checkbox"/> Lithograph <input checked="" type="checkbox"/> Other (<u>Pressure sensitive</u>) <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			

Section IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application)*		
Name Alan R. Wagner D.V.M., M.S. Alan R. Wagner, D.V.M., M.S.	Title Manager, Regulatory Affairs Agent for Antec International	Telephone No. (Include Area Code) 407/944-9803

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature Alan R. Wagner D.V.M., M.S.	3. Title Manager Regulatory Affairs Agent for Antec International	
4. Typed Name Alan R. Wagner, D.V.M., M.S.	5. Date August 8, 1995	



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☐ Other

OPP Identifier Number

228184

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name)	PM#	
5. Name and Address of Applicant (Include ZIP Code) <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(ii), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal	
				<input type="checkbox"/> Plastic	
				<input type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	
* Certification must be submitted				<input type="checkbox"/> Other (Specify) _____	
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name	Title	Telephone No. (Include Area Code)
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature	3. Title	
4. Typed Name	5. Date	

PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

PAPERWORK REDUCTION ACT NOTICE: Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, (2136), U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503.

INSTRUCTIONS: This form is to be used for all applications for new registration, and use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

1. Certification with Respect to Citation of Data (EPA Form 8570-29). [If not exempted by 40 CFR 152.81 (b) (4)];
2. Confidential Statement of Formula (EPA Form 8570-4);
3. Formulator's Exemption Statement (EPA Form 8570-27);
4. Five copies of draft labeling;
5. Three copies of any data submitted;
6. Authorization letter where applicable;
7. Matrices where applicable.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper for submission or a mockup of the proposed label. If prepared for mockup, it should be constructed in a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission.

Submission of Data - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

SPECIFIC INSTRUCTIONS: Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended reregistration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.

Block A - Check the appropriate action for which you are submitting this form.

SECTION I - This section must be completed, as applicable, for all registration actions.

1. **Company/Product Number** - Insert your Company Number, if one has been assigned by EPA. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
2. **EPA Product Manager** - If known, fill in the name and PM number of the EPA Product Manager.
3. **Proposed Classification** - Specify the proposed classification of this product.
4. **Product Name** - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
5. **Name and Address of Applicant** - The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
6. **Expedited Review** - FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

SECTION II - This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA-registered product. This section is not to be used for a new application for registration.

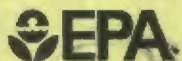
1. **Subject of submission** - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; "general label revision of use directions." Attach a separate page if additional space is needed.

SECTION III (Packaging and Container Information) - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

1. **Type of Packaging** - Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
2. **Type of Retail Container** - Indicate type of container in which product will be marketed.
3. **Location of Net Contents** - Indicate the location of the net contents information for your product.
4. **Size(s) of Retail Container** - Specify the net contents of all retail containers for your product.
5. **Location of Use Directions** - Indicate the location of the use directions for your product.
6. **Manner in which label is affixed to product** - Indicate the method product label is attached to retail container.

SECTION IV (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me-too," reregistration, etc.

- 1-5. Self-explanatory.
6. EPA Use Only.



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☐ Other

OPP Identifier Number

228184

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name)	PM#	
5. Name and Address of Applicant (Include ZIP Code) <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal	
				<input type="checkbox"/> Plastic	
				<input type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	
				<input type="checkbox"/> Other (Specify) _____	
* Certification must be submitted					
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled				<input type="checkbox"/> Other _____	

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
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2. Signature	3. Title	
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6. **Manner in which label is affixed to product** - Indicate the method product label is attached to retail container.

SECTION IV (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me-too," reregistration, etc.

- 1-5. Self-explanatory.
6. EPA Use Only.

Reviewer ID 7m ClarkSubmission No. 5489716

Data Package No. _____

CODING FORM FOR APPLICATIONS FOR REGISTRATION/AMENDMENTS

File Symbol/Reg. No. 62432-1 PM 32 Action Code 301☒ [10] Descriptor (Amend/Resubmissions only) Updated Master Label☒ [5] Intrastate Call-in ☐ (Y) Yes ☐ (N) No ☒ [15] Child-resistant Packaging ☐ (C) Certification ☐ (S) Service Person☒ [20] Registration Type:☒ (1) Conditional ☐ (2) Unconditional☐ (R) Non-residential Use Only☐ (N) Not-Applicable☒ [25] Proposed Classification: ☒ [30] Final Classification:☐ (R) Restricted ☐ (R) Restricted☐ (G) General ☐ (N) Not Classified☒ [35] Date on Application: ☒ [04] EPA Received Date:016210913
MO DAY YR016216915
MO DAY YR☒ [40] Date Received by PM017015915
MO DAY YR☒ [80] Method of Support:☐ (1) Cite-All ☐ (6) Owner Submission☐ (4) Not Applicable ☐ (7) Total Submission☐ (5) Not Submitted ☐ (8) Selective Method

Reviewers Requested:

CH

EP

PL

DEB

NDEB

TB

EEB

EFGB

DATE
SENTDUE
DATEDATE
RETURNEDRESPONSE
CODERESPONSE
DATE

☒ [115] FINAL Response
ACTION Code 37☒ [120] Response1214915
MO DAY YR75-DAY RESPONSE DUE DATE: ☒ (Y) Yes ☐ (N) No8/8/95 Submission



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

06/27/95

ALAN WAGNER
DR ALAN WAGNER, DVM, MS
2304 ANHINGA DR
KISSIMMEE FL 34743

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

PRODUCT NAME: VIRKON S
COMPANY NAME: DR ALAN WAGNER, DVM, MS
OPP IDENTIFICATION NUMBER: 191008
EPA REGISTRATION NUMBER: 62432-1
EPA RECEIPT DATE: 06/26/95

SUBJECT: RECEIPT OF AMENDMENT

DEAR REGISTRANT:

The Office of Pesticide Programs has received your application for an amendment and it has passed an administrative screen for completeness.

During the initial screen we determined that the application qualifies for fast track review. The package will now be forwarded to the Product Manager for review to determine its acceptability.

If you have any questions, please contact Ruth Douglas, Product Manager 32, at (703)-305-7964.

Sincerely,

J. Wrice

Front End Processing Staff
Information Services Branch
Program Management and Support Division

A

DR. ALAN R. WAGNER
Regulatory Affairs and Technical Services

6

Private Consultant
Clinical Investigations

2304 Anhinga Drive
Kissimmee, Florida 34743

Ph: 407/344-9803
Fax: 407/344-9980

June 20, 1995

Ms. Ruth G. Douglas (PM32)
Antimicrobial Program Branch
Registration Division (7505C)
U.S. Environmental Protection Agency
401 M Street S.W.
Washington, D.C. 20460

Subject: VirKon S (EPA Reg # 62432-1)
Master Label Update

Dear Ms. Douglas:

Please find enclosed for your review "Application For Pesticide Amendment" updating our EPA Master Label.

We have responded to your letter of May 5, 1995 and modified the updated Master Label by identifying the specific bacteria on the label and revised the name of record of the product as Virkon S by deleting the Virkon E identification. This revision was sent to you on May 24, 1995 to the attention of Ms. Marianne Clark as requested.

At this point, Ms. Douglas, I would appreciate your review of the enclosed Master Label Amendment and updates, hopefully for inclusion or attachment to the previous submissions of Master Label Amendments (June 24, 1994/Fast Track, April 11, 1995 and May 24, 1995) so as to expedite your review and approval.

I am planning a Washington, D.C. trip in the very near future and will contact you to arrange an appointment to discuss our regulatory affairs activity and progress concerning our registration and reregistration efforts.

Again, Ms. Douglas, thank you for your excellent assistance and courtesy extended to me regarding our regulatory concerns.

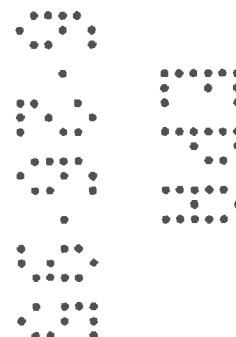
Sincerely,

Alan R. Wagner

Alan R. Wagner, D.V.M., M.S.
Agent for Antec International Ltd

ARW/mw

Enclosures



EQUINE BACTERIA

Clostridial diarrhea
Enteric Colibacillosis
Fistulous Withers (Poll Evil)
Taylorella equigenitalis
Streptococcus equi (Strangles)
Pseudomonas mallei (Glanders)
Bordetella bronchiseptica
Salmonella enteritidis

EQUINE VIRUSES

African Horse Sickness
Equine Viral Arteritis (Pink Eye)
Coital Exanthema
Myeloencephalopathy
Rhinopneumonitis

Equine Infectious Anemia (Swamp Fever)

Equine papillomatosis

Equine Contagious Abortion

Adenovirus Pneumonia

Equine Influenza (The Cough)

Parainfluenza

EQUINE FUNGI

Dermatophytosis (Ringworm)

Dermatophytosis (Mud Fever)

Fusarium moniliforme

Leukoencephalomalacia

Moldy Corn Poisoning

BOVINE BACTERIA

Listeria monocytogenes

Moraxella bovis

Erysipelothrix rhusiopathiae

Mycobacterium bovis

Haemophilus somnus

BOVINE VIRUSES

Calf rotavirus

Infective Bovine Rhinotracheitis

Bovine Viral Diarrhea

Rabies

Bovine Adenovirus Type 4

Pseudorabies

Foot and Mouth Disease

BOVINE FUNGI

Fusarium moniliforme

Antec
International

V
(Virkon logo)

VIRKON® S BROAD SPECTRUM DISINFECTANT

For Use in Cleaning and Disinfecting Industrial
Animal and Agricultural Facilities

EFFECTIVE AGAINST:

BACTERIA

Streptococcus pyogenes
Campylobacter pyloridis
Klebsiella pneumoniae
Escherichia coli
Salmonella typhimurium
Salmonella choleraesuis
Salmonella enteritidis
Pseudomonas aeruginosa
Staphylococcus aureus
Staphylococcus epidermidis
Mycoplasma gallisepticum
Clostridium perfringens
Bordetella avium

VIRUSES

Newcastle Disease
Infectious Bronchitis
Infectious Bursal Disease
Avian Laryngotracheitis
Avian Influenza
Marek's Disease
Egg Drop Syndrome
Turkey Herpes Virus
Duck Herpes Virus
Duck Viral Enteritis

FUNGI

Aspergillus flavus
Aspergillus fumigatus
Candida albicans

ACTIVE INGREDIENTS

Potassium peroxymonosulfate..... 20.4%
Sodium Chloride..... 1.5%
INERT INGREDIENTS..... 78.1%
TOTAL.....100.0%

Equivalent to 9.75% Available Chlorine

KEEP OUT OF REACH OF CHILDREN
DANGER:

See Back Panel for Additional Precautions

11 lbs (5Kg) Net Weight

ANTEC INTERNATIONAL LTD
Windham Road, Chilton Industrial Estates
Sudbury Suffolk CO10 6XD, England
Tel: (1787) 77305 Telx: 987495 Fax: (1787) 310846

SWINE BACTERIA

Bordetella bronchiseptica
Pasteurella multocida

Campylobacter coli

Campylobacter jejuni

Atrophic Rhinitis

Colibacillosis

Enteritis

Mastitis

Necrotic Enteritis

Salmonellosis

Erysipelothrix rhusiopathiae

Leptospirosis

Actinobacillus pleuropneumoniae

Treponema hyodysenteriae

Listeria monocytogenes

Clostridium perfringens

SWINE VIRUSES

Hog Cholera

Swine Influenza

Transmissible Gastroenteritis

Porcine parvovirus

Rotaviral diarrhea

Vesicular stomatitis

Pseudorabies

Porcine Reproductive and

Respiratory Syndrome (PRRS)

African Swine Fever

Foot and Mouth Disease

Rabies

SWINE FUNGI

Fusarium moniliforme

COMPANION ANIMALS

BACTERIA

Staphylococcus aureus

Streptococcus pyogenes

Klebsiella pneumoniae

Pseudomonas aeruginosa

VIRUSES

Canine Parvovirus

Distemper

Rabies

Parainfluenza

Infectious hepatitis

Oral papillomatosis

Coronavirus

Leptospira canicola

Feline parvovirus

Feline herpes

Feline calicivirus

FUNGI....

Microsporum canis

VIRKON S is a registered trademark of and manufactured by Antec International Limited

U.S. Patent No. 4822512

SIDE PANEL

BROAD SPECTRUM DISINFECTANT

VIRKON S is effective against numerous microorganisms affecting animals: viruses, gram positive and gram negative bacteria, fungi (molds and yeasts), and mycoplasma. Efficacy was determined in the presence of hard water and organic material.

CONTROLS

Viruses of Newcastle Disease, Infectious Bronchitis, Infectious Bursal Disease, Avian Laryngotracheitis, Marek's Disease, Egg Drop Syndrome, Avian Influenza, Turkey Herpes Virus and Duck Viral Enteritis. **Fungi** (molds and yeasts - *Aspergillus flavus*, *Aspergillus fumigatus* and *Candida albicans*. **Bacteria** - *Streptococcus pyogenes*, *Campylobacter pyloridis*, *Klebsiella pneumoniae*, *Escherichia coli*, *Salmonella typhimurium*, *Salmonella choleraesuis*, *Salmonella enteritidis*, *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Staphylococcus epidermidis*, *Bordetella avium*, *Mycoplasma gallisepticum* and *Necrotic Enteritis*.

DIRECTIONS FOR USE

Federal law prohibits use of this product in a manner inconsistent with its labeling.

This powder formula is easily diluted for use in manual or machine operations.

POULTRY PRODUCTION/RATITE PRODUCTION

VIRKON S is recommended for use in hatcheries, chicken houses, Ratite production and processing plants.

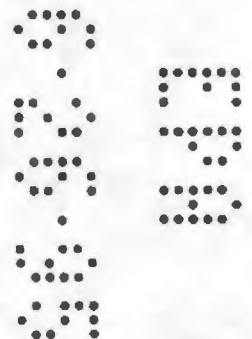
HATCHERIES: **VIRKON S** at 1% solution is generally suitable for cleaning and disinfecting hatches, setters, evaporative coolers, humidifying systems, ceiling fans, chicken houses, transfer trucks, trays, and plastic chick boxes (use 2% solution for *Mycoplasma*, *Aspergillus flavus* and *Aspergillus fumigatus*). **VIRKON S** is recommended for use in fogging (wet misting) operations as an adjunct either preceding or following regular cleaning and disinfecting procedures. **VIRKON S** at 1-2% solution is suitable. Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions.

BROILER/BREEDER HOUSES: Following removal of chickens, feed, and water troughs, remove manure and litter and spray floors and side walls with **VIRKON S** at 1% solution. Thoroughly wash waterers and feeders with a 1% solution of **VIRKON S** (use 2% solution for *Mycoplasma*, *Aspergillus flavus* and *Aspergillus fumigatus*). After contact for 10 minutes, rinse with potable water. Do not use to house poultry or employ equipment until treatment has dried.

FOR AIR SANITIZING: Use **VIRKON S** at 1-2% solution. Fog the atmosphere until surfaces are moist. Allow at least 2 hours before entering area that has been fogged.

VIRKON S passes the AOAC germicidal and detergent sanitizer test at a concentration of 0.5% (1:200) in the presence of 200 ppm hard water.

PROCESSING PLANTS: For disinfecting and cleaning walls, ceilings, and floors spray at a dilution of 1%.



SIDE PANEL CONTINUED

SWINE PRODUCTION

CONTROLS: Viruses of Hog Cholera, Swine influenza, Transmissible Gastroenteritis, Porcine Parvovirus, Vesicular Stomatitis, Pseudorabies, Porcine Reproductive and Respiratory Syndrome (PRRS) Rotoviral Diarrhea, African Swine Fever, Foot and Mouth Disease and Rabies. Bacteria of Atrophic Rhinitis, Colibacillosis, Leptospirosis, Mastitis, Necrotic Enteritis, Pleuropneumonia, Salmonellosis, *Treponema hyodysenteriae*, *Listeria monocytogenes* and *Clostridium perfringens*. Fungi: *Fusarium moniliforme*.

VIRKON S is recommended for use in farrowing pens, weaner accommodation, grower accommodation and finisher accommodation and processing plants: VIRKON S at 1% solution is generally suitable for cleansing and disinfecting (use 2% solution for *Mycoplasma*, *Aspergillus flavus* and *Aspergillus fumigatus*).

VIRKON S is recommended for use in fogging (wet misting) operations or as an adjunct either preceding or following regular cleaning and disinfecting procedures. VIRKON S at 1-2% solution is suitable. Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions.

EQUINE PRODUCTION

BROAD SPECTRUM EQUINE DISINFECTANT/DETERGENT/WASH FOR CLEANING AND DISINFECTING STABLES, EQUIPMENT AND AERIAL DISINFECTION APPLICATIONS

For cleaning and disinfection of all surfaces, equipment, utensils and instruments in Veterinary practices, kennels, stables, catteries, etc.

DIRECTIONS FOR USE

Add the contents of one VIRKON S sachet to one gallon of warm water. Solutions are stable for 7 days. Do not soak metal objects for long periods - 10 minutes is maximum necessary contact time. One gallon of solution is sufficient to treat 135 sq. ft.

CONTROLS

Viruses of African Horse Sickness, Equine Viral Arteritis (Pink Eye), Coital Exanthema, Myeloencephalopathy, Rhinopneumonitis, Equine Contagious Abortion, Equine Papillomatosis, Equine Infectious Anemia (Swamp Fever), Adenovirus Pneumonia, Parainfluenza, Equine Influenza (The Cough) and Rhinitis, Bacterial: Clostridial Diarrhea, *Salmonella enteritidis*, Enteric Colibacillosis, Fistulous Withers (Poll Evil), *Taylorella equigenitalis*, *Bordetella bronchiseptica*, *Streptococcus equi* (Strangles) and *Pseudomonas mallei* (Glanders). Fungi: Dermatophytosis (Ringworm), Dermatophylosis (Mud Fever), *Fusarium moniliforme*, Leukoencephalomalacia, and Moldy corn poisoning.

BOVINE PRODUCTION

CONTROLS: Viruses of Calf rotavirus, Infectious Bovine Rhinotracheitis, Bovine Viral Diarrhea, Rabies, Bovine Adenovirus Type 4 and Pseudorabies; Bacteria of *Listeria monocytogenes*, *Moraxella bovis*, *Erysipelothrix rhusiopathiae*, *Haemophilus somnus* and *Mycobacterium bovis*; Fungi of *Fusarium moniliforme*.

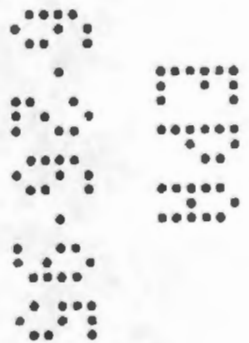
DIRECTIONS FOR USE

VirKon S is recommended for use in areas associated with bovine stabling, quarantine or feedlot facilities. VirKon S at 1% solution is generally suitable for cleansing and disinfection.

SIDE PANEL CONTINUED

COMPANION ANIMALS

CONTROLS: Viruses of Canine Parvovirus, Distemper, Rabies, Parainfluenza, Infectious hepatitis, Oral papillomatosis, Coronavirus, *Leptospira canicola*, Feline parvovirus, Feline herpes and Feline calicivirus. Bacteria of *Staphylococcus aureus*, *Streptococcus pyogenes*, *Klebsiella pneumoniae*, and *Pseudomonas aeruginosa*; Fungi of *Microsporum canis*.



BACK PANEL

VIRKON® S

DILUTION CHART

Quantity of Final Solution	1% Solution	2% Solution
American		
1 gallon	1.3 ounces	2.7 ounces
10 gallons	13.4 ounces	26.7 ounces
50 gallons	66.8 ounces	133.5 ounces
Metric		
10 liters	100 grams	200 grams
50 liters	500 grams	1000 grams
200 liters	2 kgs	4 kgs
125g	6oz	
100g	5oz	
75g	4 oz	
50g	3oz	
	2oz	
	1oz	

Brim full - contains
200g or 7 ounces

The measure cap holds when
filled level 500g or 17.5 ounces.

For **DISINFECTING** use a rate of 7.5 gallons/1000 sq. ft.

For **CLEANING AND DISINFECTING** use a rate of 15 gallons/1000 sq. ft.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER

Corrosive. Causes skin burns and irreversible eye damage. Harmful if swallowed, absorbed through skin, or inhaled. Do not get in eyes, on skin, or on clothing. Wear protective clothing and rubber gloves. Avoid breathing dust. Wear goggles, face shield, or safety glasses. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse. Refers to powder form only and not use dilution.

PRACTICAL TREATMENT

IF IN EYES: Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes. Get prompt medical attention.

IF ON SKIN: Wash with plenty of soap and water. Get medical attention if irritation persists.

IF INHALED or symptoms of coughing, choking, or wheezing are troublesome, remove to fresh air and seek medical attention.

IF SWALLOWED: Drink promptly a large quantity of water. Avoid alcohol. Get immediate medical attention.

NOTICE OF PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

STORAGE AND DISPOSAL - Store in a cool, dry place in tightly closed container away from children. Always replace lid after use. Wash empty container thoroughly and dispose of in trash.

ANTEC INTERNATIONAL LTD

Windham Road, Chilton Industrial Estates

Sudbury Suffolk CO10 6XD, England

Tel: (1787) 77305 Telx: 987495 Fax: (1787) 310846

EPA Reg. No. 62432-1

EPA Est. No. 62432-1EN-001

fl - Please read instructions on reverse before completing form.

(A) EPA		United States Environmental Protection Agency Office of Pesticide Programs (H7505C) Washington, DC 20460		<input type="checkbox"/> Registration <input checked="" type="checkbox"/> Amendment <input type="checkbox"/> Other		OPP Identifier Number 191008	
Section I							
1. Company/Product Number 62432		2. EPA Product Manager Ms. Ruth G. Douglas		3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted			
4. Company/Product (Name) VIRKON S		PM# 32					
5. Name and Address of Applicant (Include ZIP Code) Antec International Ltd. Chilton Industrial Estates Sudbury, Suffolk CO106XD ENGLAND <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____					
Section II							
<input checked="" type="checkbox"/> Amendment - Explain below		Final printed labels in response to Agency letter dated _____					
<input type="checkbox"/> Resubmission in response to Agency letter dated _____		"Me Too" Application.					
<input type="checkbox"/> Notification - Explain below.		Other - explain below.					
Explanation: Use additional page(s) if necessary. (For section I and Section II.) 1. Submission of amendment for Master Label Update 2. Five (5) copies of amended Master Label							
Section III							
1. Material This Product Will Be Packaged In:							
Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No		Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		2. Type of Container <input checked="" type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____	
Certification must be submitted.		If "Yes," Unit Package wgt. No. per container		If "Yes," Package wgt. No. per container			
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) of Retail Container 2.5 Kg, 5.0 Kg, 2.5 Kg, 35 grams, 50 grams		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product			
6. Manner In Which Label Is Affixed To Product		<input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input checked="" type="checkbox"/> Other (Pressure Sensitive)			
Section IV							
1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)							
Name Alan R. Wagner, D.V.M., M.S.		Title Manager, Regulatory Affairs Agent for Antec International		Telephone No. (Include Area Code) 407/344-9803			
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.						6. Date Application Received (Stamped)	
2. Signature Alan R. Wagner D.V.M., M.S.		3. Title Manager Regulatory Affairs Agent for Antec International					
4. Typed Name Alan R. Wagner, D.V.M., M.S.		5. Date June 20, 1995					

PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

PAPERWORK REDUCTION ACT NOTICE: Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503.

INSTRUCTIONS: This form is to be used for all applications for new registration, and use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

1. Certification with Respect to Citation of Data (EPA Form 8570-29). [If not exempted by 40 CFR 152.81 (b) (4)];
2. Confidential Statement of Formula (EPA Form 8570-4);
3. Formulator's Exemption Statement (EPA Form 8570-27);
4. Five copies of draft labeling;
5. Three copies of any data submitted;
6. Authorization letter where applicable;
7. Matrices where applicable.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper or a mockup of the proposed label. If prepared as a mockup, it should be constructed in such a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission.

Submission of Data - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

SPECIFIC INSTRUCTIONS: Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended registration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.

Block A - Check the appropriate action for which you are submitting this form.

SECTION I - This section must be completed, as applicable, for all registration actions.

1. **Company/Product Number** - Insert your Company Number, if one has been assigned by EPA. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
2. **EPA Product Manager** - If known, fill in the name and PM number of the EPA Product Manager.
3. **Proposed Classification** - Specify the proposed classification of this product.
4. **Product Name** - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
5. **Name and Address of Applicant** - The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
6. **Expedited Review** - FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

SECTION II - This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA-registered product. This section is not to be used for a new application for registration.

1. **Subject of submission** - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; general label revision of use directions." Attach a separate page if additional space is needed.

SECTION III: (Packaging and Container Information) - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

1. **Type of Packaging** - Check the appropriate block if your product will be packaged in the indicated packaging types.
2. **Indicate the size of the individual packets and number per retail container.**
3. **Type of Retail Container** - Indicate type of container in which product will be marketed.
4. **Location of Net Contents** - Specify the net contents of all retail containers for your product.
5. **Size(s) of Retail Container** - Specify the net contents of all retail containers for your product.
6. **Location of Use Directions** - Indicate the location of the use directions for your product.
7. **Manner in which label is affixed to product** - Indicate the method product label is attached to retail container.

SECTION IV: (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., new products, registration, resubmission, "me-too," reregistration, etc.

- 1-5. Self-explanatory.
6. EPA Use Only.

Reviewer ID Douglas
Submission No. 5486847
Data Package No. _____

CODING FORM FOR APPLICATIONS FOR REGISTRATION/AMENDMENTS

File Symbol/Reg. No. 62432-1 PM 32 Action Code 300

10 Descriptor (Amend/Resubmissions only) Amended label

5 Intrastate Call-in ☐ (Y) Yes 15 Child-resistant Packaging ☐ (C) Certification
☐ (N) No ☐ (S) Service Person

20 Registration Type: ☐ (1) Conditional ☐ (2) Unconditional ☐ (R) Non-residential Use Only
☐ (N) Not-Applicable

25 Proposed Classification: 30 Final Classification:
☐ (R) Restricted ☐ (R) Restricted
☐ (G) General ☐ (N) Not Classified

35 Date on Application: 04 EPA Received Date: 04 Date Received by PM
014 11 9 15 014 11 8 9 15 014 21 1 9 15
MO DAY YR MO DAY YR MO DAY YR

80 Method of Support:
☐ (1) Cite-All ☐ (6) Owner Submission
☐ (4) Not Applicable ☐ (7) Total Submission
☐ (5) Not Submitted ☐ (8) Selective Method

Reviewers Requested:	DATE SENT	DUE DATE	DATE RETURNED	RESPONSE CODE	RESPONSE DATE
CH					
EF					
PL					
DEB					
NDEB					
TB					
EEB					
EFGB					

115 FINAL Response ACTION Code 37 120 Response 121495
per telecon superceded by
75-DAY RESPONSE DUE DATE: ☐ (Y) Yes ☐ (N) No
Aug. 8, 1995 submission

DR. ALAN R. WAGNER
Regulatory Affairs and Technical Services

Private Consultant
Clinical Investigations

2304 Anhinga Drive
Kissimmee, Florida 34743

Ph: 407/344-9803
Fax: 407/344-9980

April 11, 1995

Ms. Ruth G. Douglas (PM32)
Antimicrobial Program Branch
Registration Division (7505C)
U.S. Environmental Protection Agency
401 M Street S.W
Washington, D.C. 20460

Subject: VirKon S (EPA Reg. # 62432-1)

Dear Ms. Douglas:

Please find for your review "Application For Pesticide Amendment" updating our EPA Master Label, approval date December 1, 1994.

We have highlighted the modifications on the updated Master Label as you requested and have submitted 5 draft labels reflecting the modifications.

Again, I wish to thank you for your excellent assistance and courtesy extended to me concerning our regulatory affairs activities.

Anxious to see you soon during my next visit to your agency.

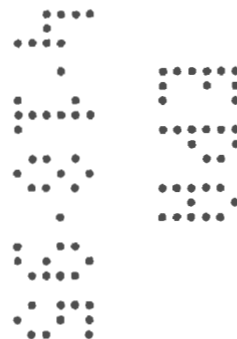
Sincerely,

Alan

Alan R. Wagner, D.V.M., M.S.
Agent for Antec International Ltd.

ARW/mw

Enclosures



EQUINE BACTERIA

Clostridial diarrhea
Salmonellosis
Enteric Colibacillosis
Fistulous Withers (Poll Evil)
Taylorella equigenitalis
Strangles
Glanders
Listeria monocytogenes
Bordatella bronchiseptica
Streptococcus equi
Salmonella enteritidis

EQUINE VIRUSES

African Horse Sickness
Equine Viral Arteritis (Pink Eye)
Coital Exanthema
Myeloencephalopathy
Rhinopneumonitis
Equine Infectious Anemia (Swamp Fever)
Equine Papillomatosis
Equine Contagious Abortion
Adenovirus Pneumonia
Equine Influenza (The Cough)
Rhinitis
Parainfluenza

EQUINE FUNGI

Dermatophytosis (Ringworm)
Dermatophylosis (Mud Fever)
Fusarium moniliforme
Leukoencephalomalacia
Moldy Corn Poisoning

BOVINE BACTERIA

Listeria monocytogenes
Moraxella bovis
Erysipelothrix rhusiopathiae
Mycobacterium bovis
Haemophilus somnus
BOVINE VIRUSES
Calf rotavirus
Infective Bovine Rhinotracheitis
Bovine Viral Diarrhea
Rabies

Bovine Adenovirus Type 4

Pseudorabies
Foot & Mouth Disease

BOVINE FUNGI

Fusarium moniliforme

Antec
International

V
(Virkon logo)

VIRKON® S BROAD SPECTRUM DISINFECTANT

For Use in Cleaning and Disinfecting Industrial
Animal and Agricultural Facilities

EFFECTIVE AGAINST:

BACTERIA

Streptococcus pyogenes
Campylobacter ptyoridis
Klebsiella pneumoniae
Escherichia coli
Salmonella typhimurium
Salmonella choleraesuis
Salmonella enteritidis
Pseudomonas aeruginosa
Staphylococcus aureus
Staphylococcus epidermidis
Mycoplasma gallisepticum
Clostridium perfringens
Bordetella avium

VIRUSES

Newcastle Disease
Infectious Bronchitis
Infectious Bursal Disease
Avian Laryngotracheitis
Avian Influenza
Marek's Disease
Egg Drop Syndrome
Turkey Herpes Virus
Duck Herpes Virus
Duck Viral Enteritis

FUNGI

Aspergillus flavus
Aspergillus fumigatus
Candida albicans

ACTIVE INGREDIENTS

Potassium peroxymonosulfate.....	20.4%
Sodium Chloride.....	1.5%
INERT INGREDIENTS.....	78.1%
TOTAL.....	100.0%

Equivalent to 9.75% Available Chlorine

KEEP OUT OF REACH OF CHILDREN
DANGER:

See Back Panel for Additional Precautions

11 lbs (5Kg) Net Weight

ANTEC INTERNATIONAL LTD
Windham Road, Chilton Industrial Estates
Sudbury Suffolk CO10 6XD, England
Tel: (0787) 77305 Telx: 987495 Fax: (0787) 310846

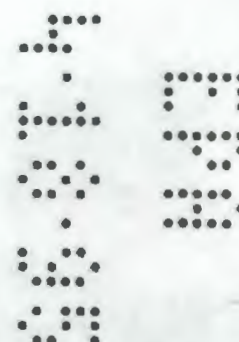
SWINE BACTERIA

Bordatella bronchiseptica
Pasteurella multocida
Campylobacter Spp.
Erysipelothrix rhusiopathiae
Leptospira Spp.
Actinobacillus pleuropneumoniae
Treponema hyodysenteriae
Listeria monocytogenes
Clostridium perfringens
SWINE VIRUSES
Hog Cholera
Swine Influenza
Transmissible Gastroenteritis
Porcine parvovirus
Rotaviral diarrhea
Vesicular stomatitis
Pseudorabies
Porcine Reproductive and
Respiratory Syndrome (PRRS)
African Swine Fever

Rabies

SWINE FUNGI

Fusarium moniliforme



VIRKON S is a registered trademark of and manufactured by Antec International Limited

U.S. Patent No. 4822512

SIDE PANEL

BROAD SPECTRUM DISINFECTANT

VIRKON S is effective against numerous microorganisms affecting animals: viruses, gram positive and gram negative bacteria, fungi (molds and yeasts), and mycoplasma. Efficacy was determined in the presence of hard water and organic material.

CONTROLS

Viruses of Newcastle Disease, Infectious Bronchitis, Infectious Bursal Disease, Avian Laryngotracheitis, Avian Influenza, **Turkey Herpes Virus and Duck Viral Enteritis**. **Fungi** (molds and yeasts - *Aspergillus flavus*, *Aspergillus fumigatus* and *Candida albicans*. **Bacteria** - *Streptococcus pyogenes*, *Campylobacter pyloridis*, *Klebsiella pneumoniae*, *Escherichia coli*, *Salmonella typhimurium*, *Salmonella choleraesuis*, *Salmonella enteritidis*, *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Staphylococcus epidermidis*, *Bordetella avium*, *Mycoplasma gallisepticum* and **Necrotic Enteritis**.

DIRECTIONS FOR USE

Federal law prohibits use of this product in a manner inconsistent with its labeling.

This powder formula is easily diluted for use in manual or machine operations.

POULTRY PRODUCTION/RATITE PRODUCTION

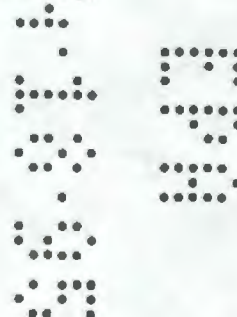
VIRKON S is recommended for use in hatcheries, chicken houses, Ratite production and processing plants.

HATCHERIES: **VIRKON S** at 1% solution is generally suitable for cleaning and disinfecting hatches, setters, evaporative coolers, humidifying systems, ceiling fans, chicken houses, transfer trucks, trays, and plastic chick boxes (use 2% solution for *Mycoplasma*, *Aspergillus flavus* and *Aspergillus fumigatus*). **VIRKON S** is recommended for use in fogging (wet misting) operations as an adjunct either preceding or following regular cleaning and disinfecting procedures. **VIRKON S** at 1-2% solution is suitable. Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions.

BROILER/BREEDER HOUSES: Following removal of chickens, feed, and water troughs, remove manure and litter and spray floors and side walls with **VIRKON S** at 1% solution. Thoroughly wash waterers and feeders with a 1% solution of **VIRKON S** (use 2% solution for *Mycoplasma*, *Aspergillus flavus* and *Aspergillus fumigatus*). After contact for 10 minutes, rinse with potable water. Do not use to house poultry or employ equipment until treatment has dried.

FOR AIR SANITIZING: Use **VIRKON S** at 1-2% solution. Fog the atmosphere until surfaces are moist. Allow at least 2 hours before entering area that has been fogged.

PROCESSING PLANTS: For disinfecting and cleaning walls, ceilings, and floors spray at a dilution of 1%.



SIDE PANEL CONTINUED

SWINE PRODUCTION

CONTROLS: Viruses of Hog Cholera, Porcine Parvo Disease, Vesicular Stomatitis, Pseudorabies, Porcine Reproductive and Respiratory Syndrome (PRRS) Rotoviral Diarrhea, Swine influenza, Foot and Mouth Disease and TGE. Bacteria of Arthritis, Meningitis, Atrophic Rhinitis, Pasteurellosis, Colibacillosis, Enteritis, Erysipelas, Leptospirosis, Mastitis, Necrotic Enteritis, Pleuropneumonia, Salmonellosis and Swine Dysentery. Fungi (molds and yeasts) *Aspergillus flavus*, *Aspergillus fumigatus* and *Candida albicans*.

VIRKON S is recommended for use in farrowing pens, weaner accommodation, grower accommodation and finisher accommodation and processing plants: VIRKON S at 1% solution is generally suitable for cleansing and disinfecting (use 2% solution for *Mycoplasma*, *Aspergillus flavus* and *Aspergillus fumigatus*).

VIRKON S is recommended for use in fogging (wet misting) operations or as an adjunct either preceding or following regular cleaning and disinfecting procedures. VIRKON S at 1-2% solution is suitable. Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions.

EQUINE PRODUCTION

APPLICATIONS

For cleaning and disinfection of all surfaces, equipment, utensils and instruments in Veterinary practices, kennels, stables, catteries, etc.

DIRECTIONS FOR USE

Add the contents of one sachet to one gallon of warm water. In cases of parvovirus challenge, add the contents of two sachets to one gallon of water. Solutions are stable for 7 days. Do not soak metal objects for long periods - 10 minutes is maximum necessary contact time.

CONTROLS

Viruses of African Horse Sickness, Equine Viral Arteritis (Pink Eye), Coital Exanthema, Myeloencephalopathy, Rhinopneumonitis, Equine Contagious Abortion, Equine Papillomatosis, Equine Infectious Anemia (Swamp Fever), Adenovirus Pneumonia, Parainfluenza, Equine Influenza (The Cough) and Rhinitis, Bacterial; Clostridial Diarrhea, Salmonellosis, Enteric Colibacillosis, Fistulous Withers (Poll Evil), *Taylorella equigenitalis*, *Bordetella bronchiseptica*, *Streptococcus equi*, Mycotoxic Disease, *Pasteurella*, Strangles and Glanders. Fungi; Dermatophytosis (Ringworm), Dermatophytosis (Mud Fever), *Fusarium moniliforme*, Leukoencephalomalacia, and Moldy corn poisoning.

BOVINE PRODUCTION

CONTROLS: Viruses of Calf rotavirus, Infectious Bovine Rhinotracheitis, Bovine Viral Diarrhea, Rabies, Bovine Adenovirus Type 4 and Pseudorabies; Bacteria of *Listeria monocytogenes*, *Moraxella bovis*, *Erysipelothrix rhusiopathiae*, *Haemophilus somnus* and *Mycobacterium bovis*; Fungi of *Fusarium moniliforme*.

DIRECTIONS FOR USE

VirKon S is recommended for use in areas associated with bovine stabling, quarantine or feedlot facilities. VirKon S at 1% solution is generally suitable for cleansing and disinfection.

COMPANION ANIMALS

CONTROLS: Viruses of Canine Parvovirus, Distemper, Rabies, Parainfluenza, Infectious hepatitis, Oral papillomatosis, Coronavirus, and *Leptospira canicola*; Bacteria of *Staphylococcus aureus*, *Streptococcus pyogenes*, *Klebsiella pneumoniae*, and *Pseudomonas aeruginosa*; Fungi of *Microsporum canis*. Viruses of Feline parvovirus, Feline herpes and Feline calicivirus.

BACK PANEL

VIRKON® S

DILUTION CHART

Quantity of Final Solution	1% Solution	2% Solution
American		
1 gallon	1.3 ounces	2.7 ounces
10 gallons	13.4 ounces	26.7 ounces
50 gallons	66.8 ounces	133.5 ounces
Metric		
10 liters	100 grams	200 grams
50 liters	500 grams	1000 grams
200 liters	2 kgs	4 kgs

125g	6oz
100g	5oz
75g	4 oz
50g	3oz
	2oz
	1oz

Brim full - contains
200g or 7 ounces

The measure cap holds when
filled level 500g or 17.5 ounces.

For DISINFECTING use a rate of 7.5 gallons/1000 sq. ft.

For CLEANING AND DISINFECTING use a rate of 15 gallons/1000 sq. ft.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER

Corrosive. Causes skin burns and irreversible eye damage. Harmful if swallowed, absorbed through skin, or inhaled. Do not get in eyes, on skin, or on clothing. Wear protective clothing and rubber gloves. Avoid breathing dust. Wear goggles, face shield, or safety glasses. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

PRACTICAL TREATMENT

IF IN EYES: Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes. Get prompt medical attention.

IF ON SKIN: Wash with plenty of soap and water. Get medical attention if irritation persists.

IF INHALED or symptoms of coughing, choking, or wheezing are troublesome, remove to fresh air and seek medical attention.

IF SWALLOWED: Drink promptly a large quantity of water. Avoid alcohol. Get immediate medical attention.

NOTICE OF PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

STORAGE AND DISPOSAL - Store in a cool, dry place in tightly closed container away from children. Always replace lid after use. Wash empty container thoroughly and dispose of in trash.

ANTEC INTERNATIONAL LTD
Windham Road, Chilton Industrial Estates
Sudbury Suffolk CO10 6XD, England
Tel: (0787) 77305 Telx: 987495 Fax: (0787) 310846

EPA Reg. No. 62432-1

EPA Est. No. 62432-EN-001

EQUINE BACTERIA
 Clostridial diarrhea
 Salmonellosis
 Enteric Colibacillosis
 Fistulous Withers (Poll Evil)
Taylorella equigenitalis
 Strangles
 Glanders
Listeria monocytogenes

Bordatella bronchiseptica
Streptococcus equi
Salmonella enteritidis

EQUINE VIRUSES
 African Horse Sickness
 Equine Viral Arteritis (Pink Eye)
 Coital Exanthema
 Myeloencephalopathy
 Rhinopneumonitis
 Equine Infectious Anemia (Swamp Fever)
 Equine Papillomatosis
 Equine Contagious Abortion
 Adenovirus Pneumonia
 Equine Influenza (The Cough)
 Rhinitis
 Parainfluenza

EQUINE FUNGI
 Dermatophytosis (Ringworm)
 Dermatophylosis (Mud Fever)
Fusarium moniliforme
Leukoencephalomalacia

Moldy Corn Poisoning

BOVINE BACTERIA

Listeria monocytogenes
Moraxella bovis
Erysipelothrix rhusiopathiae
Mycobacterium bovis
Haemophilus somnus
BOVINE VIRUSES
 Calf rotavirus
 Infective Bovine Rhinotracheitis
 Bovine Viral Diarrhea
 Rabies

Bovine Adenovirus Type 4

Pseudorabies
 Foot & Mouth Disease

BOVINE FUNGI

Fusarium moniliforme

**Antec
 International**

**V
 (Virkon logo)**

**VIRKON® S
 BROAD SPECTRUM DISINFECTANT**

For Use in Cleaning and Disinfecting Industrial
 Animal and Agricultural Facilities

EFFECTIVE AGAINST:

BACTERIA

Streptococcus pyogenes
Campylobacter plyoridas
Klebsiella pneumoniae
Escherichia coli
Salmonella typhimurium
Salmonella choleraesuis
Salmonella enteritidis
Pseudomonas aeruginosa
Staphylococcus aureus
Staphylococcus epidermidis
Mycoplasma gallisepticum
Clostridium perfringes
Bordetella avium

VIRUSES

Newcastle Disease
 Infectious Bronchitis
 Infectious Bursal Disease
 Avian Laryngotracheitis
 Avian Influenza
 Marek's Disease
 Egg Drop Syndrome
 Turkey Herpes Virus
 Duck Herpes Virus
 Duck Viral Enteritis

FUNGI

Aspergillus flavus
Aspergillus fumigatus
Candida albicans

ACTIVE INGREDIENTS

Potassium peroxymonosulfate..... 20.4%
 Sodium Chloride..... 1.5%
INERT INGREDIENTS..... 78.1%
TOTAL.....100.0%

Equivalent to 9.75% Available Chlorine

**KEEP OUT OF REACH OF CHILDREN
 DANGER:**

See Back Panel for Additional Precautions

11 lbs (5Kg) Net Weight

ANTEC INTERNATIONAL LTD
 Windham Road, Chilton Industrial Estates
 Sudbury Suffolk CO10 6XD, England
 Tel: (0787) 77303 Telx: 987495 Fax: (0787) 310846

SWINE BACTERIA

Bordatella bronchiseptica
Pasteurella multocida
Campylobacter Spp.
Erysipelothrix rhusiopathiae
Leptospira Spp.
Actinobacillus pleuropneumoniae
Treponema hyodysenteriae
Listeria monocytogenes

Clostridium perfringes

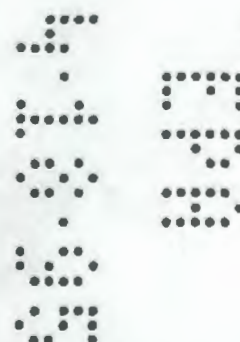
SWINE VIRUSES

Hog Cholera
 Swine Influenza
 Transmissible Gastroenteritis
 Porcine parvovirus
 Rotaviral diarrhea
 Vesicular stomatitis
 Pseudorabies
 Porcine Reproductive and
 Respiratory Syndrome(PRRS)
 African Swine Fever

Rabies

SWINE FUNGI

Fusarium moniliforme



VIRKON S is a registered trademark of and manufactured by Antec International Limited

U.S. Patent No. 4822512

SIDE PANEL

BROAD SPECTRUM DISINFECTANT

VIRKON S is effective against numerous microorganisms affecting animals: viruses, gram positive and gram negative bacteria, fungi (molds and yeasts), and mycoplasma. Efficacy was determined in the presence of hard water and organic material.

CONTROLS

Viruses of Newcastle Disease, Infectious Bronchitis, Infectious Bursal Disease, Avian Laryngotracheitis, Avian Influenza, Turkey Herpes Virus and Duck Viral Enteritis. **Fungi** (molds and yeasts - *Aspergillus flavus*, *Aspergillus fumigatus* and *Candida albicans*). **Bacteria** - *Streptococcus pyogenes*, *Campylobacter pyloridis*, *Klebsiella pneumoniae*, *Escherichia coli*, *Salmonella typhimurium*, *Salmonella choleraesuis*, *Salmonella enteritidis*, *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Staphylococcus epidermidis*, *Bordetella avium*, *Mycoplasma gallisepticum* and **Necrotic Enteritis**.

DIRECTIONS FOR USE

Federal law prohibits use of this product in a manner inconsistent with its labeling.

This powder formula is easily diluted for use in manual or machine operations.

POULTRY PRODUCTION/RATITE PRODUCTION

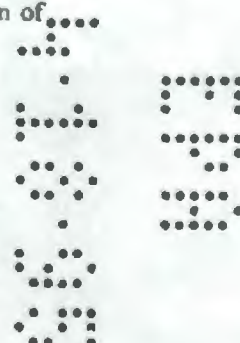
VIRKON S is recommended for use in hatcheries, chicken houses, Ratite production and processing plants.

HATCHERIES: **VIRKON S** at 1% solution is generally suitable for cleaning and disinfecting hatches, setters, evaporative coolers, humidifying systems, ceiling fans, chicken houses, transfer trucks, trays, and plastic chick boxes (use 2% solution for *Mycoplasma*, *Aspergillus flavus* and *Aspergillus fumigatus*). **VIRKON S** is recommended for use in fogging (wet misting) operations as an adjunct either preceding or following regular cleaning and disinfecting procedures. **VIRKON S** at 1-2% solution is suitable. Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions.

BROILER/BREEDER HOUSES: Following removal of chickens, feed, and water troughs, remove manure and litter and spray floors and side walls with **VIRKON S** at 1% solution. Thoroughly wash waterers and feeders with a 1% solution of **VIRKON S** (use 2% solution for *Mycoplasma*, *Aspergillus flavus* and *Aspergillus fumigatus*). After contact for 10 minutes, rinse with potable water. Do not use to house poultry or employ equipment until treatment has dried.

FOR AIR SANITIZING: Use **VIRKON S** at 1-2% solution. Fog the atmosphere until surfaces are moist. Allow at least 2 hours before entering area that has been fogged.

PROCESSING PLANTS: For disinfecting and cleaning walls, ceilings, and floors spray at a dilution of 1%.



SIDE PANEL CONTINUED

SWINE PRODUCTION

CONTROLS: Viruses of Hog Cholera, Porcine Parvo Disease, Vesicular Stomatitis, Pseudorabies, Porcine Reproductive and Respiratory Syndrome (PRRS) Rotoviral Diarrhea, Swine influenza, Foot and Mouth Disease and TGE. Bacteria of Arthritis, Meningitis, Atrophic Rhinitis, Pasteurellosis, Colibacillosis, Enteritis, Erysipelas, Leptospirosis, Mastitis, Necrotic Enteritis, Pleuropneumonia, Salmonellosis and Swine Dysentery. Fungi (molds and yeasts) *Aspergillus flavus*, *Aspergillus fumigatus* and *Candida albicans*.

VIRKON S is recommended for use in farrowing pens, weaner accommodation, grower accommodation and finisher accommodation and processing plants: VIRKON S at 1% solution is generally suitable for cleansing and disinfecting (use 2% solution for *Mycoplasma*, *Aspergillus flavus* and *Aspergillus fumigatus*).

VIRKON S is recommended for use in fogging (wet misting) operations or as an adjunct either preceding or following regular cleaning and disinfecting procedures. VIRKON S at 1-2% solution is suitable. Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions.

EQUINE PRODUCTION

APPLICATIONS

For cleaning and disinfection of all surfaces, equipment, utensils and instruments in Veterinary practices, kennels, stables, catteries, etc.

DIRECTIONS FOR USE

Add the contents of one sachet to one gallon of warm water. In cases of parvovirus challenge, add the contents of two sachets to one gallon of water. Solutions are stable for 7 days. Do not soak metal objects for long periods - 10 minutes is maximum necessary contact time.

CONTROLS

Viruses of African Horse Sickness, Equine Viral Arteritis (Pink Eye), Coital Exanthema, Myeloencephalopathy, Rhinopneumonitis, Equine Contagious Abortion, Equine Papillomatosis, Equine Infectious Anemia (Swamp Fever), Adenovirus Pneumonia, Parainfluenza, Equine Influenza (The Cough) and Rhinitis, Bacterial; Clostridial Diarrhea, Salmonellosis, Enteric Colibacillosis, Fistulous Withers (Poll Evil), *Taylorella equigenitalis*, *Bordetella bronchiseptica*, *Streptococcus equi*, Mycotoxic Disease, *Pasteurella*, Strangles and Glanders. Fungi; Dermatophytosis (Ringworm), Dermatophytosis (Mud Fever), *Fusarium moniliforme*, Leukoencephalomalacia, and Moldy corn poisoning.

BOVINE PRODUCTION

CONTROLS: Viruses of Calf rotavirus, Infectious Bovine Rhinotracheitis, Bovine Viral Diarrhea, Rabies, Bovine Adenovirus Type 4 and Pseudorabies; Bacteria of *Listeria monocytogenes*, *Moraxella bovis*, *Erysipelothrix rhusiopathiae*, *Haemophilus somnus* and *Mycobacterium bovis*; Fungi of *Fusarium moniliforme*.

DIRECTIONS FOR USE

VirKon S is recommended for use in areas associated with bovine stabling, quarantine or feedlot facilities. VirKon S at 1% solution is generally suitable for cleansing and disinfection.

COMPANION ANIMALS

CONTROLS: Viruses of Canine Parvovirus, Distemper, Rabies, Parainfluenza, Infectious hepatitis, Oral papillomatosis, Coronavirus, and *Leptospira canicola*; Bacteria of *Staphylococcus aureus*, *Streptococcus pyogenes*, *Klebsiella pneumoniae*, and *Pseudomonas aeruginosa*; Fungi of *Microsporum canis*. Viruses of Feline parvovirus, Feline herpes and Feline calicivirus.

BACK PANEL**VIRKON® S****DILUTION CHART**

<u>Quantity of Final Solution</u>	<u>1% Solution</u>	<u>2% Solution</u>
American		
1 gallon	1.3 ounces	2.7 ounces
10 gallons	13.4 ounces	26.7 ounces
50 gallons	66.8 ounces	133.5 ounces
Metric		
10 liters	100 grams	200 grams
50 liters	500 grams	1000 grams
200 liters	2 kgs	4 kgs

125g
100g
75g
50g

6oz
5oz
4 oz
3oz
2oz
1oz

Brim full - contains
200g or 7 ounces

The measure cap holds when
filled level 500g or 17.5 ounces.

For DISINFECTING use a rate of 7.5 gallons/1000 sq. ft.

For CLEANING AND DISINFECTING use a rate of 15 gallons/1000 sq. ft.

PRECAUTIONARY STATEMENTS**HAZARDS TO HUMANS AND DOMESTIC ANIMALS****DANGER**

Corrosive. Causes skin burns and irreversible eye damage. Harmful if swallowed, absorbed through skin, or inhaled. Do not get in eyes, on skin, or on clothing. Wear protective clothing and rubber gloves. Avoid breathing dust. Wear goggles, face shield, or safety glasses. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

PRACTICAL TREATMENT

IF IN EYES: Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes. Get prompt medical attention.

IF ON SKIN: Wash with plenty of soap and water. Get medical attention if irritation persists.

IF INHALED or symptoms of coughing, choking, or wheezing are troublesome, remove to fresh air and seek medical attention.

IF SWALLOWED: Drink promptly a large quantity of water. Avoid alcohol. Get immediate medical attention.


NOTICE OF PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

STORAGE AND DISPOSAL - Store in a cool, dry place in tightly closed container away from children. Always replace lid after use. Wash empty container thoroughly and dispose of in trash.

ANTEC INTERNATIONAL LTD
Windham Road, Chilton Industrial Estates
Sudbury Suffolk CO10 6XD, England
Tel: (0787) 77305 Telex: 987495 Fax: (0787) 310846

EPA Reg. No. 62432-1

EPA Est. No. 62432-EN-001

(A) 	United States Environmental Protection Agency Office of Pesticide Programs (H7505C) Washington, DC 20460 Application for Pesticide:	<input type="checkbox"/> Registration	OPP Identifier Number 191010
		<input checked="" type="checkbox"/> Amendment	
		<input type="checkbox"/> Other	

Section I

1. Company/Product Number 62432	2. EPA Product Manager Ms. Ruth G. Douglas	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) VirKon S	PM# 32	
5. Name and Address of Applicant (Include ZIP Code) Antec International Ltd. Chilton Industrial Estates Sudbury, Suffolk CO10 6XD ENGLAND <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section II

<input checked="" type="checkbox"/> Amendment - Explain below	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Submission of Admendment For Updating Master EPA Label Approved
December 1, 1994.

Section III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input type="checkbox"/> Metal	
				<input checked="" type="checkbox"/> Plastic	
				<input type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	
				<input type="checkbox"/> Other (Specify) _____	
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) of Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner In Which Label Is Affixed To Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input checked="" type="checkbox"/> Other (<u>Pressure sensitive</u>)			

Section IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name Alan R. Wagner, D.V.M., M.S.	Title Manager, Regulatory Affairs Agent for Antec International	Telephone No. (Include Area Code) 407/344-9803	
2. Signature Alan R. Wagner, D.V.M., M.S.		3. Title Manager, Regulatory Affairs Agent for Antec International	
4. Typed Name Alan R. Wagner, D.V.M., M.S.		5. Date April 11, 1995	
I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)	

PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

PAPERWORK REDUCTION ACT NOTICE: Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503.

INSTRUCTIONS: This form is to be used for all applications for new registration, end use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

1. Certification with Respect to Citation of Data (EPA Form 8570-29). [If not exempted by 40 CFR 152.81 (b) (4)];
2. Confidential Statement of Formula (EPA Form 8570-4);
3. Formulator's Exemption Statement (EPA Form 8570-27);
4. Five copies of draft labeling;
5. Three copies of any data submitted;
6. Authorization letter where applicable;
7. Matrices where applicable.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper or a mockup of the proposed label. If prepared as a mockup, it should be constructed in such a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission.

Submission of Data - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

SPECIFIC INSTRUCTIONS: Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended registration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.

Block A - Check the appropriate action for which you are submitting this form.

SECTION I - This section must be completed, as applicable, for all registration actions.

1. **Company/Product Number** - Insert your Company Number, if one has been assigned by EPA. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
2. **EPA Product Manager** - If known, fill in the name and PM number of the EPA Product Manager.
3. **Proposed Classification** - Specify the proposed classification of this product.
4. **Product Name** - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
5. **Name and Address of Applicant** - The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
6. **Expedited Review** - FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

SECTION II - This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA-registered product. This section is not to be used for a new application for registration.

1. **Subject of submission** - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; general label revision of use directions." Attach a separate page if additional space is needed.

SECTION III (Packaging and Container Information) - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

1. **Type of Packaging** - Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
2. **Type of Retail Container** - Indicate type of container in which product will be marketed.
3. **Location of Net Contents** - Specify the net contents of all retail containers for your product.
4. **Size(s) of Retail Container** - Specify the net contents of all retail containers for your product.
5. **Location of Use Directions** - Indicate the location of the use directions for your product.
6. **Manner in which label is affixed to product** - Indicate the method product label is attached to retail container.

SECTION IV (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me-too," reregistration, etc.

- 1-5. Self-explanatory.
6. EPA Use Only.

Reviewer ID

MCLark

Submission No.

5498165

Data Package No.

CODING FORM FOR APPLICATIONS FOR REGISTRATION/AMENDMENTS

File Symbol/Reg. No. 62432-1 PM 32 Action Code 301

10 Descriptor (Amend/Resubmissions only) Amended appl. - revision

5 Intrastate Call-in (Y) Yes 15 Child-resistant Packaging (C) Certification
(N) No (S) Service Person

20 Registration Type:

(1) Conditional (2) Unconditional

25 Proposed Classification: 30 Final Classification:

(R) Restricted (R) Restricted
(G) General (N) Not Classified

35 Date on Application: 04 EPA Received Date:

MO DAY YR 0 5 2 4 9 5 MO DAY YR 0 5 3 1 9 5

40 Date Received by PM

MO DAY YR 0 6 1 3 9 5

80 Method of Support:

(1) Cite-All (6) Owner Submission
(4) Not Applicable (7) Total Submission
(5) Not Submitted (8) Selective Method

Reviewers Requested:

CH

EF

PL

DEB

NDEB

TB

EEB

EFGB

DATE
SENTDUE
DATEDATE
RETURNEDRESPONSE
CODERESPONSE
DATE115 FINAL Response
ACTION Code 17

120 Response

DEC 11 1995

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

DEC 11 1995

Dr. Alan R. Wagner, D.V.M., M. S.
Agent for Antec International Limited
2821 River Park Drive
Columbus, OH 43220

Dear Dr. Wagner:

Subject: Virkon S
EPA Registration No. 62432-1
Your Resubmission Dated May 24, 1995

This is in response to your resubmission of revised labeling for the subject product.

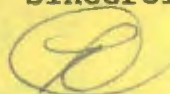
The labeling referred to above submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended is acceptable provided that you make the following revisions before you release the product for shipment bearing the amended labeling.

1. Delete "Leptospirosis". This is the disease and not the name of the organism.
2. Delete "Campylobacter coli" and "Campylobacter jejuni." These are also human pathogens. Therefore data would be required.

A stamped copy is enclosed for your records. Submit one copy of the final printed label.

If you have any questions about these comments, please call Marianne Clark at (703) 305-7879.

Sincerely yours,



Ruth Douglas
Product Manager (32)
Antimicrobial Program Branch
Registration Division (7505C)

CONCURRENCES

SYMBOL								
SURNAME								
DATE								

EQUINE BACTERIA

Clostridial diarrhea
Salmonellosis
Enteric Colibacillosis
Fistulous Withers (Poll Evil)
Taylorella equigenitalis,
Strangles
Glanders

EQUINE VIRUSES

African Horse Sickness
African Viral Arteritis (Pink Eye)
Coital Exanthema
Myeloencephalopathy
Rhinopneumonitis
Equine Contagious Abortion
Equine Papillomatosis
Equine Infectious Anemia (Swamp Fever)
Adenovirus Pneumonia
Equine Influenza (The Cough)
Rhinitis

EQUINE FUNGUS

Dermatophytosis (Ringworm)
Dermatophytosis (Mud Fever)

**Antec
International**

V

(Virkon logo)

VIRKON® S BROAD SPECTRUM DISINFECTANT

**For Use in Cleaning and Disinfecting Industrial
Animal and Agricultural Facilities**

EFFECTIVE AGAINST:

BACTERIA

Streptococcus pyogenes
Campylobacter pyloridis
Klebsiella pneumoniae
Escherichia coli
Salmonella typhimurium
Salmonella choleraesuis
Pseudomonas aeruginosa
Staphylococcus aureus
Staphylococcus epidermidis
Mycoplasma gallisepticum
Clostridium perfringens

VIRUSES OF

Newcastle Disease
Infectious Bronchitis
Infectious Bursal Disease

Avian Laryngotracheitis
Avian Influenza
Marek's Disease
Egg Drop Syndrome

FUNGI

Aspergillus flavus
Candida albicans

ACTIVE INGREDIENTS

Potassium peroxymonosulfate..... 20.4%
Sodium Chloride..... 1.5%
INERT INGREDIENTS..... 78.1%
TOTAL..... 100.0%

Equivalent to 9.75% Available Chlorine

**KEEP OUT OF REACH OF CHILDREN
DANGER:**

See Back Panel for Additional Precautions

11 lbs (5Kg) Net Weight

ANTEC INTERNATIONAL LTD
Windham Road, Chilton Industrial Estates
Sudbury Suffolk CO10 6XD, England
Tel: (0787) 77305 Telx: 987495 Fax: (0787) 310846

VIRKON S is a registered trademark of and manufactured by Antec International Limited

SWINE BACTERIA

Bordetella bronchiseptica
Pasteurella multocida
~~Campylobacter coli~~
~~Campylobacter jejuni~~
Erysipelothrix rhusiopathiae,
~~Leptospirosis~~
Actinobacillus pleuropneumoniae
Treponema hyodysenteriae.

SWINE VIRUSES

Hog cholera
Swine influenza
TGE, Blue eye
Porcine parvovirus
Rotaviral diarrhea
Vesicular stomatitis
Pseudorabies

U.S. Patent No. 4,822,512

BROAD SPECTRUM DISINFECTANT

VIRKON S is effective against numerous microorganisms affecting animals: viruses, gram positive and gram negative bacteria, fungi (molds and yeasts), and mycoplasma. Efficacy was determined in the presence of hard water and organic material.

CONTROLS

Viruses of Newcastle Disease, Infectious Bronchitis, Infectious Bursal Disease, Laryngotracheitis, and Avian Influenza.

Fungi (molds and yeasts) - *Aspergillus flavus* and *Candida albicans*.

Bacteria - *Streptococcus pyogenes*, *Campylobacter pyloridis*, *Klebsiella pneumoniae*, *Escherichia coli*, *Salmonella typhimurium*, *Salmonella choleraesuis*, *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Staphylococcus epidermidis*, *Mycoplasma gallisepticum*.

DIRECTIONS FOR USE

Federal law prohibits use of this product in a manner inconsistent with its labeling.

This powder formula is easily diluted for use in manual or machine operations.

VIRKON S is recommended for use in hatcheries, chicken houses, and processing plants.

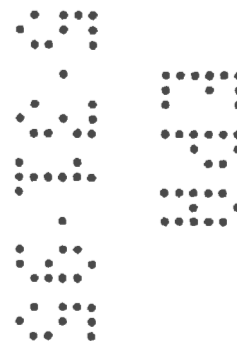
HATCHERIES: **VIRKON S** at 1% solution is generally suitable for cleaning and disinfecting hatchers, setters, evaporative coolers, humidifying systems, ceiling fans, chicken houses, transfer trucks, trays, and plastic chick boxes (use 2% solution for *Mycoplasma* and *Aspergillus flavus*).

VIRKON S is recommended for use in fogging (wet misting) operations as an adjunct either preceding or following regular cleaning and disinfecting procedures. **VIRKON S** at 1-2% solution is suitable. Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions.

BROILER/BREEDER HOUSES: Following removal of chickens, feed, and water troughs, remove manure and litter and spray floors and side walls with **VIRKON S** at 1% solution. Thoroughly wash waterers and feeders with a 1% solution of **VIRKON S** (use 2% solution for *Mycoplasma* and *Aspergillus flavus*). After contact for 10 minutes, rinse with potable water. Do not use to house poultry or employ equipment until treatment has dried.

FOR AIR SANITIZING: Use **VIRKON S** at 1-2% solution. Fog the atmosphere until surfaces are moist. Allow at least 2 hours before entering area that has been fogged.

PROCESSING PLANTS: For disinfecting and cleaning walls, ceilings, and floors spray at a dilution of 1%.



SIDE PANEL CONTINUED

SWINE PRODUCTION

CONTROLS: Viruses of Hog Cholera, Porcine Parvo Disease, Vesicular Stomatitis, Pseudorabies, Porcine Reproductive and Respiratory Syndrome (PRRS) Rotoviral Diarrhea, Swine influenza, Foot and Mouth Disease and TGE. Bacteria of Arthritis, Meningitis, Atrophic Rhinitis, Pasteurellosis, Colibacillosis, Enteritis, Erysipelas, Leptospirosis, Mastitis, Necrotic Enteritis, Pleuropneumonia, Salmonellosis and Swine Dysentery. Fungi (molds and yeasts) *Aspergillus flavus*, *Aspergillus fumigatus* and *Candida albicans*.

VIRKON S is recommended for use in farrowing pens, weaner accommodation, grower accommodation and finisher accommodation and processing plants: VIRKON S at 1% solution is generally suitable for cleansing and disinfecting (use 2% solution for *Mycoplasma*, *Aspergillus flavus* and *Aspergillus fumigatus*).

VIRKON S is recommended for use in fogging (wet misting) operations or as an adjunct either preceding or following regular cleaning and disinfecting procedures. VIRKON S at 1-2% solution is suitable. Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions.

EQUINE PRODUCTION

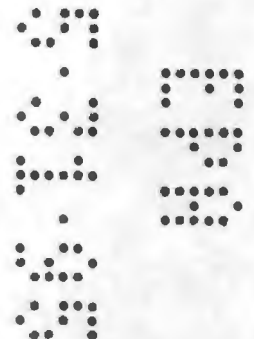
VIRKON S will destroy all viruses, bacteria and fungi which cause diseases including EVA, Herpes 123, strangles, Mud Fever, Skin Lesions, Warts and Ringworm.

DIRECTIONS FOR USE

For Topical Use On Animal; Shampoo infected area with VIRKON S using a clean sponge. Rinse with clean water. Apply three times a day. Repeat as necessary. Stables, Horse Boxes, Feed Rooms, Thoroughly dry clean. Then wash the area manually or with pressure washer with a 1% VIRKON S. Tack, Grooming Equipment, Feeders, Drinkers; Wash by hand using 1% VIRKON S. Rinse with clean water. Blankets and Rugs; Shampoo by hand or spray lightly with a hand sprayer and leave to dry. Shake or vacuum to remove residue. Aerial Spraying to control airborne diseases: By using a knapsack sprayer with fine setting or a VIRKON S SPRAY APPLICATION SYSTEM which automatically sprays the area. Spray for 2-3 minutes twice daily, first thing in the morning and last thing at night.

CONTROLS

Viruses of African Horse Sickness, Equine Viral Arteritis (Pink Eye), Coital Exanthema, Myeloencephalopathy, Rhinopneumonitis, Equine Contagious Abortion, Equine Papillomatosis, Equine Infectious Anemia (Swamp Fever) Adenovirus Pneumonia, *Taylorella equigenitalis*, Equine Influenza (The Cough) and Rhinitis. **Bacterial:** Clostridial Diarrhea, Salmonellosis, Enteric Colibacillosis, Fistulous Withers (Poll Evil), Strangles and Glanders. **Fungi:** Dermatophytosis (Ringworm) and Dermatophytosis (Mud Fever).



VIRKON® S**DILUTION CHART**

Quantity of Final Solution	1% Solution	2% Solution
American		
1 gallon	1.3 ounces	2.7 ounces
10 gallons	13.4 ounces	26.7 ounces
50 gallons	66.8 ounces	133.5 ounces
Metric		
10 liters	100 grams	200 grams
50 liters	500 grams	1000 grams
200 liters	2 kgs	4 kgs

125g
100g
75g
50g

6oz
5oz
4 oz
3oz
2oz
1oz

Brim full - contains
200g or 7 ounces

The measure cap holds when
filled level 500g or 17.5 ounces.

For DISINFECTING use a rate of 7.5 gallons/1000 sq. ft.

For CLEANING AND DISINFECTING use a rate of 15 gallons/1000 sq. ft.

PRECAUTIONARY STATEMENTS**HAZARDS TO HUMANS AND DOMESTIC ANIMALS****DANGER**

Corrosive. Causes skin burns and irreversible eye damage. Harmful if swallowed, absorbed through skin, or inhaled. Do not get in eyes, on skin, or on clothing. Wear protective clothing and rubber gloves. Avoid breathing dust. Wear goggles, face shield, or safety glasses. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

PRACTICAL TREATMENT

IF IN EYES: Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes. Get prompt medical attention.

IF ON SKIN: Wash with plenty of soap and water. Get medical attention if irritation persists.

IF INHALED or symptoms of coughing, choking, or wheezing are troublesome, remove to fresh air and seek medical attention.

IF SWALLOWED: Drink promptly a large quantity of water. Avoid alcohol. Get immediate medical attention.

NOTICE OF PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

STORAGE AND DISPOSAL - Store in a cool, dry place in tightly closed container. Always replace lid after use. Wash empty container thoroughly and dispose of in trash.

ANTEC INTERNATIONAL LTD
Windham Road, Chilton Industrial Estates
Sudbury Suffolk CO10 6XD, England

Tel: (0787) 77305 Telex: 987495 Fax: (0787) 310846

EPA Reg. No. 62432-1

ACCEPTED
with COMMENTS
in EPA Letter Dated:

DEC 11 1995

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide
registered under EPA Reg. No. 62432-1

EPA Est. No. 62432-EN-001

62432-1

DR. ALAN R. WAGNER
Regulatory Affairs and Technical Services

Private Consultant
Clinical Investigations

2304 Anhinga Drive
Kissimmee, Florida 34743

Ph: 407/344-9803
Fax: 407/344-9980

May 24, 1995

Ms. Ruth G. Douglas (PM32)
Antimicrobial Program Branch
Registration Division (7505C)
U.S. Environmental Protection Agency
401 M Street S.W.
Washington, D.C. 20460

Attn: Ms. Marianne Clark

Subject: Virkon S (EPA Reg # 62432)
Response To Your Letter of May 5, 1995

Dear Ms. Clark:

In accordance with your letter of May 5, 1995 and our telephone conversation of May 24, 1995, please find enclosed Application for Pesticide Amendment relating to our submission of June 24, 1994. As stated in your letter,

1. We have revised the proposed claims, identifying the specific bacteria on our label and
2. we have the name of record of this product as Virkon S throughout the text and deleted the Virkon E identification.

Incidentally, Ms. Clark, I am concerned that my current address has not been entered into the EPA computer record since your letter was directed to my previous address. Notification of address change (as indicated above) was formally submitted.

I do wish to thank you for your assistance on this date and the courtesy extended to me. I hope to visit with you and Ms. Douglas on my next visit to Washington and EPA.

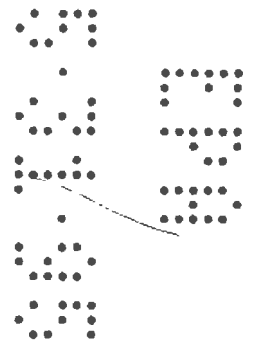
Sincerely,

Alan R. Wagner, D.V.M., M.S.

Alan R. Wagner, D.V.M., M.S.
Agent for Antec International Ltd

ARW/mw

Attachments



(A)		EPA		United States Environmental Protection Agency Office of Pesticide Programs (H7505C) Washington, DC 20460		Registration <input checked="" type="checkbox"/> Amendment <input type="checkbox"/> Other		OPP Identifier Number 191011	
Section I									
1. Company/Product Number 62432				2. EPA Product Manager Ms. Ruth G. Douglas			3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted		
4. Company/Product (Name) VIRKON S				PM# # 32					
5. Name and Address of Applicant (Include ZIP Code) Antec International Ltd Chilton Industrial Estate Sudbury, Suffolk CO10 6XD ENGLAND <input type="checkbox"/> Check if this is a new address				6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____					
Section II									
<input checked="" type="checkbox"/> Amendment - Explain below Resubmission in response to Agency letter dated 5/5/95 <input type="checkbox"/> Notification - Explain below.				<input type="checkbox"/> Final printed labels in response to Agency letter dated _____ <input type="checkbox"/> "Me Too" Application. <input type="checkbox"/> Other - explain below.					
Explanation: Use additional page(s) if necessary. (For section I and Section II.) 1. Revision of identification of microbial entities, i.e., specie. 2. Correction of product name to conform with VIRKON S (name of record for this product) throughout text of Master Label.									
Section III									
1. Material This Product Will Be Packaged In:									
Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No		Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes," Unit Package wgt. _____ No. per container _____		Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes," Package wgt. _____ No. per container _____		2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____			
* Certification must be submitted.									
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container			4. Size(s) of Retail Container 2.5 Kg, 5.0 Kg, 2.5 Kg 25 grams, 50 grams			5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product			
6. Manner In Which Label Is Affixed To Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			<input checked="" type="checkbox"/> Other (Pressure Sensitive)						
Section IV									
1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)									
Name Alan R. Wagner, D.V.M., M.S.			Title Manager, Regulatory Affairs Agent for Antec International Ltd.			Telephone No. (Include Area Code) 407/344-9803			
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.									
2. Signature Alan R. Wagner, D.V.M., M.S.			3. Title Manager, Regulatory Affairs Agent for Antec International Ltd.						
4. Typed Name Alan R. Wagner, D.V.M., M.S.			5. Date May 24, 1995						
6. Date Application Received (Stamped)									

PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

PAPERWORK REDUCTION ACT NOTICE: Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503.

INSTRUCTIONS: This form is to be used for all applications for new registration, and use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

1. Certification with Respect to Citation of Data (EPA Form 8570-29). [If not exempted by 40 CFR 152.81 (b) (4)];
2. Confidential Statement of Formula (EPA Form 8570-4);
3. Formulator's Exemption Statement (EPA Form 8570-27);
4. Five copies of draft labeling;
5. Three copies of any data submitted;
6. Authorization letter where applicable;
7. Matrices where applicable.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper or a mockup of the proposed label. If prepared as a mockup, it should be constructed in such a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission.

Submission of Data - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

SPECIFIC INSTRUCTIONS: Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended registration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.

Block A - Check the appropriate action for which you are submitting this form.

SECTION I - This section must be completed, as applicable, for all registration actions.

1. **Company/Product Number** - Insert your Company Number, if one has been assigned by EPA. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
2. **EPA Product Manager** - If known, fill in the name and PM number of the EPA Product Manager.
3. **Proposed Classification** - Specify the proposed classification of this product.
4. **Product Name** - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
5. **Name and Address of Applicant** - The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
6. **Expedited Review** - FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

SECTION II - This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA-registered product. This section is not to be used for a new application for registration.

1. **Subject of submission** - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; general label revision of use directions." Attach a separate page if additional space is needed.

SECTION III (Packaging and Container Information) - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

1. **Type of Packaging** - Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
2. **Type of Retail Container** - Indicate type of container in which product will be marketed.
3. **Location of Net Contents** - Specify the net contents of all retail containers for your product.
4. **Location of Retail Container** - Specify the net contents of all retail containers for your product.
5. **Location of Use Directions** - Indicate the location of the use directions for your product.
6. **Manner in which label is affixed to product** - Indicate the method product label is attached to retail container.

SECTION IV (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me-too," reregistration, etc.

- 1-5. Self-explanatory.
6. EPA Use Only.

Reviewer ID

Submission No.

Data Package No.

McClark
Sample
5470454

CODING FORM FOR APPLICATIONS FOR REGISTRATION/AMENDMENTS

File Symbol/Reg. No. 62432-1 PM 302 Action Code 300

10 Descriptor (Amend/Resubmissions only) Submission of Updated Labels

5 Intrastate Call-in ☐ (Y) Yes ☒ (N) No 15 Child-resistant Packaging ☐ (C) Certification ☐ (S) Service Person

20 Registration Type: ☒ (1) Conditional ☐ (2) Unconditional ☐ (R) Non-residential Use Only ☐ (N) Not-Applicable

25 Proposed Classification: ☐ (R) Restricted ☐ (G) General 30 Final Classification: ☐ (R) Restricted ☐ (N) Not Classified

35 Date on Application: 01 6 24 94 04 EPA Received Date: 01 7 01 94 40 Date Received by PM: 01 7 21 94
MO DAY YR MO DAY YR MO DAY YR

80 Method of Support: ☐ (1) Cite-All ☐ (6) Owner Submission ☐ (4) Not Applicable ☐ (7) Total Submission ☐ (5) Not Submitted ☐ (8) Selective Method

Reviewers Requested:	DATE SENT	DUE DATE	DATE RETURNED	RESPONSE CODE	RESPONSE DATE
CH					
EF					
PL					
DEB					
NDEB					
TB					
EEB					
EFGB					

115 FINAL Response ACTION Code 12

120 Response

MAY 05 1995
MO DAY YR

75-DAY RESPONSE DUE DATE: ☐ (Y) Yes ☐ (N) No

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

MAY 05 1995

Dr. Alan R. Wagner, D.V.M., M.S.
Agent for Antec International Limited
Chilton Industrial Estate
Sudbury Suffolk CO10 6XD
England

Dear Dr. Wagner:

Subject: Virkon S
EPA Registration No. 62432-1
Your Amendment Dated June 24, 1994

This is in response to your amendment of revised labeling with additional uses for the subject product. The following comments apply.

Labeling:

The proposed labeling is unacceptable for the following reasons:

1. The proposed claims such as 'clostridium spp., Leptospira spp, Campylobacter ssp' are unacceptable, the specific bacteria must be mentioned.
2. The name of record for this product is "Virkon S." Throughout the label text wherever reference is made to a product name, instead of referring to Virkon S or Virkon E, indicate "this product". Only composite/master labeling (with all the uses) bearing the basic product name should be submitted for review. We do not review or stamp additional brand name labeling, such as a label with the name "Virkon E" or any other name other than "Virkon S."

CONCURRENCES

SYMBOL								
SURNAME								
DATE								

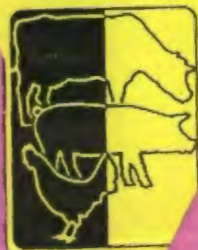
If you have any questions about these comments, please call Marianne Clark at (703) 305-7879.

Sincerely yours,



Ruth Douglas
Product Manager (32)
Antimicrobial Program Branch
Registration Division (7505C)

durvet



VirKon® S

BROAD SPECTRUM DISINFECTANT

For Use in Cleaning and Disinfecting Industrial
Animal and Agricultural Facilities

EFFECTIVE AGAINST

BACTERIA	VIRUSES OF	FUNGI
Streptococcus pyogenes Campylobacter pyloridis Klebsiella pneumoniae Escherichia coli Salmonella typhimurium Salmonella choleraesuis Pseudomonas aeruginosa Staphylococcus aureus Staphylococcus epidermidis Mycoplasma gallisepticum Clostridium spp	Newcastle Disease Infectious Bronchitis Infectious Bursal Disease Avian Laryngotracheitis Avian Influenza Marek's Disease Egg Drop Syndrome	Aspergillus flavus Candida albicans

ACTIVE INGREDIENTS

Potassium peroxymonosulfate	20.4%
Sodium Chloride	1.5%
INERT INGREDIENTS	78.1%
TOTAL	100.0%

Equivalent to 9.75% Available Chlorine

**KEEP OUT OF REACH OF CHILDREN
DANGER:**

See Back Panel for Additional Precautions

10lbs Net Weight

Distributed By:



301 Baybrook Street, Thomasville, GA 31792

Made in England by Antec International Limited

VirKon S is a registered trademark of and manufactured by
Antec International Limited U.S. Patent No. 4822512

durvet



VirKon® S

BROAD SPECTRUM DISINFECTANT

For Use in Cleaning and Disinfecting Industrial
Animal and Agricultural Facilities

EFFECTIVE AGAINST

BACTERIA	VIRUSES OF	FUNGI
Streptococcus pyogenes Staphylococcus aureus Klebsiella pneumoniae Escherichia coli Salmonella typhimurium Salmonella choleraesuis Pseudomonas aeruginosa Staphylococcus epidermidis Mycoplasma spp Bordetella bronchiseptica Pasteurella multocida Campylobacter spp Erysipelothrix rhusiopathiae Leptospira spp Clostridium spp Actinobacillus pleuropneumoniae Treponema hyodysenteriae	Hog cholera Swine Influenza TGE Blue eye Porcine parvovirus Rotaviral diarrhoea Vesicular stomatitis Pseudorabies	Aspergillus flavus Candida albicans

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DANGER:**

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Antec International Limited U.S. Patent No. 4822512

10 lbs

BROAD SPECTRUM DISINFECTANT

VIRKON S is effective against numerous microorganisms affecting animals: viruses, Gram positive and Gram negative bacteria, fungi (molds and yeasts), and Mycoplasma. Efficacy was determined in the presence of hard water and organic material.

DIRECTION FOR USE

Federal law prohibits use of this product in a manner inconsistent with its labeling.

This powder formula is easily diluted for use in manual or machine operations.

POULTRY PRODUCTION

VIRKON S is recommended for use in hatcheries, in chicken houses, and in processing plants.

CONTROLS: Viruses of Newcastle Disease, Infectious Bronchitis, Infectious Bursal Disease, Laryngotracheitis Avian Influenza, Marek's Disease and Egg Drop Syndrome. Fungi: Aspergillus flavus and Candida albicans. Bacteria: Streptococcus pyogenes, Campylobacter pyloridis, Infectious Bronchitis, Klebsiella pneumoniae, Escherichia coli, Salmonella typhimurium, Salmonella choleraesuis, Pseudomonas aeruginosa, Staphylococcus aureus, Staphylococcus epidermidis, Mycoplasma gallisepticum, Necrotic enteritis.

HATCHERIES: VIRKON S at 1% solution is generally suitable for cleaning and disinfecting hatcheries, setters, evaporative coolers, humidifying systems, ceiling fans, chicken houses, transfer trucks, trays, and plastic chick boxes (use 2% solution for Mycoplasma and Aspergillus flavus).

VIRKON S is recommended for use in fogging (wet misting) operations as an adjunct either preceding or following regular cleaning and disinfecting procedures. VIRKON S at 1-2% solution is suitable. Fog (wet mist) until the area is moist using automatic wet foggers according to manufacturer's use directions.

BROILER/BREEDER HOUSES: Following removal of chickens, feed and water troughs, remove manure and litter and spray floors and side walls with VIRKON S at 1%. Thoroughly wash waterers and feeders with a 1% solution of VIRKON S (use 2% solution for Mycoplasma and Aspergillus flavus). After contact for ten minutes, rinse with potable water. Do not use to house poultry or employ equipment until the treatment has dried.

SWINE PRODUCTION

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VIRKON is recommended for use in farrowing pens, weaner accommodation grower accommodation and finisher accommodation and processing plants: VIRKON S at 1% solution is generally suitable for cleaning and disinfecting (use 2% solution for Mycoplasma and Aspergillus flavus).

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FOR AIR SANITIZING: Use VIRKON S at 1-2% solution. Fog the atmosphere until surfaces are moist. Allow at least 2 hours before entering area that has been fogged.

PROCESSING PLANTS: For disinfecting and cleaning walls, ceilings, and floors spray at a dilution of 1%.

STORAGE & DISPOSAL: Store in a cool, dry place in tightly closed container. Always replace lid after use. Wash empty container thoroughly and dispose of in trash.

VirKon® S

DILUTION CHART

Quantity of Final Solution	1% Solution	2% Solution
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50 gallons	66.8 ounces	133.5 ounces



For DISINFECTING use a rate of 7.5 gallons/1000 sq. ft.
For CLEANING AND DISINFECTING use a rate of 15 gallons/1000 sq. ft.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER

Corrosive. Causes skin burns and irreversible eye damage. Harmful if swallowed, absorbed through skin, or inhaled. Do not get in eyes, on skin, or on clothing. Wear protective clothing and rubber gloves. Avoid breathing dust. Wear goggles, face shield, or safety glasses. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

PRACTICAL TREATMENT

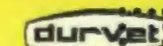
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IF INHALED or symptoms of coughing, choking, or wheezing are troublesome, remove to fresh air and seek medical attention.

IF SWALLOWED: Drink promptly a large quantity of water. Avoid alcohol. Get immediate medical attention.

NOTICE OF PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.



Manufactured by

Durvet Inc. Blue Springs, Missouri, 64015-1-800-821-5570
EPA Reg. No. 62432-1-12261. EPA Est. No. 62432-1-12261

Made in England by Antec International Limited

VirKon S

BROAD SPECTRUM DISINFECTANT
VIRKON S is effective against numerous microorganisms affecting animals: viruses, Gram positive and Gram negative bacteria, fungi (molds and yeasts), and Mycoplasma. Efficacy was determined in the presence of hard water and organic material.

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CONTROLS: Viruses of Newcastle Disease, Infectious Bronchitis, Infectious Bursal Disease, Laryngotracheitis, Avian Influenza, Marek's Disease and Egg Drop Syndrome. Fungi: *Aspergillus flavus* and *Candida albicans*. Bacteria: *Streptococcus pyogenes*, *Campylobacter pyloridis*, *Escherichia coli*, *Salmonella typhimurium*, *Salmonella choleraesuis*, *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Staphylococcus epidermidis*, *Mycoplasma gallisepticum*, *Necrotic enteritis*.

HATCHERIES: VIRKON S at 1% solution is generally suitable for cleaning and disinfecting hatcheries, setters, evaporative coolers, humidifying systems, ceiling fans, chicken houses, transfer trucks, trays, and plastic chick boxes (use 2% solution for *Mycoplasma* and *Aspergillus* flatus).

VIRKON S is recommended for use in logging (wet misting) operations as an adjunct either preceding or following regular cleaning and disinfecting procedures. VIRKON S at 1-2% solution is suitable fog (wet mist) until the area is moist using automatic wet foggers according to manufacturer's use directions.

Continued on reverse side.

durvet



VirKon S

BROAD SPECTRUM DISINFECTANT
For Use in Cleaning and Disinfecting Industrial Animal and Agricultural Facilities
EFFECTIVE AGAINST SWINE & POULTRY PATHOGENS

BACTERIA	VIRUSES OF	FUNGI
<i>Streptococcus pyogenes</i> <i>Campylobacter pyloridis</i> <i>Klebsiella pneumoniae</i> <i>Escherichia coli</i> <i>Salmonella typhimurium</i> <i>Salmonella choleraesuis</i> <i>Pseudomonas aeruginosa</i> <i>Staphylococcus aureus</i> <i>Staphylococcus epidermidis</i> <i>Mycoplasma gallisepticum</i> <i>Clostridium</i> spp. <i>Bordetella bronchiseptica</i> <i>Pasteurella multocida</i> <i>Campylobacter</i> spp. <i>Erysipelothrix rhusiopathiae</i> <i>Leptospira</i> spp. <i>Actinobacillus pleuropneumoniae</i> <i>Treponema hyodysenteriae</i>	Newcastle Disease Infectious Bronchitis Infectious Bursal Disease Avian Laryngotracheitis Avian Influenza Marek's Disease Egg Drop Syndrome Hog cholera Swine influenza TGE Blue eye Porcine parvovirus Rotaviral diarrhoea Vesicular stomatitis Pseudorabies	<i>Aspergillus flavus</i> <i>Candida albicans</i>

ACTIVE INGREDIENTS	
Potassium peroxydisulfate	20.4%
Sodium Chloride	1.5%
INERT INGREDIENTS	
TOTAL	78.1%
Equivalent to 9.75% Available Chlorine	

5lbs
Net Weight

KEEP OUT OF REACH OF CHILDREN

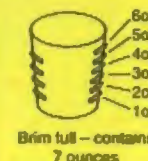
DANGER:

See Side Panel for Additional Precautions

VirKon S

DILUTION CHART

Quantity of Final Solution American	1% Solution	2% Solution
1 gallon	1.3 ounces	2.7 ounces
10 gallons	13.4 ounces	26.7 ounces
50 gallons	66.8 ounces	133.5 ounces



The measure cap holds when filled level 17.5 ounces.

For DISINFECTING use a rate of 7.5 gallons/1000 sq. ft.

For CLEANING AND DISINFECTING use a rate of 15 gallons/100 sq. ft.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER

Corrosive. Causes skin burns and irreversible eye damage. Harmful if swallowed, absorbed through skin, or inhaled. Do not get in eyes, on skin, or on clothing. Wear protective clothing and rubber gloves. Avoid breathing dust. Wear goggles, face shield, or safety glasses. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

PRACTICAL TREATMENT

IF IN EYES: Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes. Get prompt medical attention.

IF ON SKIN: Wash with plenty of soap and water. Get medical attention if irritation persists.

IF INHALED: or symptoms of coughing, choking, or wheezing are troublesome, remove to fresh air and seek medical attention.

IF SWALLOWED: Drink promptly a large quantity of water. Avoid alcohol. Get immediate medical attention.

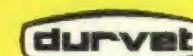
NOTICE OF PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

Distributed by



301 Baybrook Street, Thomasville, GA 31792

Manufactured for



Durvet Inc. Blue Springs, Missouri, 64015-1-800-821-5570
EPA Reg. No. 62432-1-12281. EPA Est. No. 62432-EN-001

VirKon is a registered trademark of and manufactured by
Antec International Limited U.S. Patent No. 4822512
Made in England by Antec International Limited

DIRECTIONS FOR USE CONTINUED

BROILER/BREEDER HOUSES:

Following removal of chickens, feed and water troughs, remove manure and litter and spray floors and side walls with VIRKON S at 1%. Thoroughly wash waterers and feeders with a 1% solution of VIRKON S (use 2% solution for *Mycoplasma* and *Aspergillus* flatus). After contact for ten minutes, rinse with potable water. Do not use to house poultry or employ equipment until the treatment has dried.

SWINE PRODUCTION

CONTROLS: Viruses of Blue Eye, Hog Cholera, Porcine Parvo Disease, Vesicular Stomatitis, Pseudorabies, Rotaviral Diarrhoea, Swine Influenza, Foot and Mouth Disease and TGE. Bacteria of Anthrax, Meningitis, Atrophic Rhinitis, Pasteurellosis, Colibacillosis, Enteritis, Erysipelas, Leptospirosis, Mastitis, Necrotic Enteritis, Pleuropneumonia, Salmonellosis and Swine Dysentery. Fungi (molds and yeasts): *Aspergillus flavus* and *Candida albicans*.

VIRKON is recommended for use in farrowing pens, weaner accommodation grower accommodation and finisher accommodation and processing plants. VIRKON S at 1% solution is generally suitable for cleaning and disinfecting (use 2% solution for *Mycoplasma* and *Aspergillus* flatus).

VIRKON S is recommended for use in logging (wet misting) operations or as an adjunct either preceding or following regular cleaning and disinfecting procedures. VIRKON S at 1-2% solution is suitable fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions.

FOR AIR SANITIZING: Use VIRKON S at 1-2% solution. Fog the atmosphere until surfaces are moist. Allow at least 2 hours before entering area that has been fogged.

STORAGE & DISPOSAL: Store in a cool, dry place in tightly closed container. Always replace lid after use. Wash empty container thoroughly and dispose of in trash.

8/17/94

98

DP BARCODE: D206282

CASE: 001751
SUBMISSION: S470454

DATA PACKAGE RECORD
BEAN SHEET

DATE: 08/08/94
Page 1 of 1

*** CASE/SUBMISSION INFORMATION ***

CASE TYPE: REGISTRATION ACTION: 300 ADMN-LBL REV AMND NO DATA
RANKING : 5 POINTS ()
CHEMICALS: 063604 Potassium peroxymonosulfate 20.4000%
013905 Sodium chloride 01.5000%

ID#: 062432-00001 VIRKON S
COMPANY: 062432 ANTEC INTERNATIONAL LTD
PRODUCT MANAGER: 32 RUTH DOUGLAS 703-305-7964 ROOM: CM2 278
PM TEAM REVIEWER: ~~BARBARA PRINGLE~~ mclark 703-305-6484 ROOM: CM2 280
RECEIVED DATE: 07/01/94 DUE OUT DATE: 09/29/94

*** DATA PACKAGE INFORMATION ***

DP BARCODE: 206282 EXPEDITE: N DATE SENT: 08/08/94 DATE RET.: / /
CHEMICAL: 063604 Potassium peroxymonosulfate
DP TYPE: 001 Submission Related Data Package

CSF: N LABEL: Y
ASSIGNED TO DATE IN DATE OUT ADMIN DUE DATE: 09/22/94
DIV : RD / / / / NEGOT DATE: / /
BRAN: AB / / / / PROJ DATE: / /
SECT: EETMS / / / /
REVR : / / / /
CONTR: / / / /

*** DATA REVIEW INSTRUCTIONS ***

Review revised label with additional uses

*** DATA PACKAGE EVALUATION ***

No evaluation is written for this data package

*** ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION ***

DP BC BRANCH/SECTION DATE OUT DUE BACK INS CSF LABEL

Rejected
J. Vantings
8/22/94

M. Nieves 8/10

EFFICACY EVALUATION AND TECHNICAL MANAGEMENT SECTION

EFFICACY REVIEW -I

ANTIMICROBIAL PROGRAM BRANCH

IN 8-8-94 OUT 8-17-94

Reviewed by Michael Nieves Date 8-17-94

EPA Reg. No. or File Symbol 62432-1

EPA Petition or BUP No. None

Date Division Received 7-1-94

Type Product Disinfectant (Animal & Agriculture)

MRID No(s) None

Product Manager R. Douglas (PM 31)

Product Name Virkon S

Company Name Antec International LTD

Submission Purpose The submission is an application to add additional uses.

Type Formulation Powder

Active Ingredients(s) %

Potassium peroxymonosulfate.....	20.4
Sodium chloride.....	1.5

EFFICACY EVALUATION AND TECHNICAL MANAGEMENT SECTION

EFFICACY REVIEW -II

ANTIMICROBIAL PROGRAM BRANCH

EPA Reg. No. or File Symbol 62432-1

EPA Petition or EUP No. None

Date Division Received 7-1-94

Type Product Disinfectant (Animal & Agriculture)

MRID No(s) None

Product Manager R. Douglas (PM 31)

Product Name Virkon S

Company Name Antec International LTD

- 200.0 **Introduction:**
- 200.1 **Uses:**
See attached proposed label dated 7-1-94.
- 200.2 **Background Information:**
The submission is an application to add additional uses.
- 200.3 **Factors Affecting Amount/Type of Data Required:**
None
- 201.0 **Data Summary**
None
- 201.1 **Abstract of Test Reports:**
None
- 201.2 **Brief Description of Tests:**
None
- 201.3 **Data Summaries**
None
- 201.4 **Other Summarized Results:**
See Recommendations under 202.0.

202.0 Recommendations

202.1 Efficacy Supported By The Data:

No efficacy data were submitted for this amendment.

203.0 Labeling:

The proposed labeling is unacceptable for the following reasons:

1. The registrant is proposing disinfecting claims against certain microorganisms that are equine and swine pathogens. Some of the new microorganisms mentioned in the proposed labeling are also pathogens against humans, therefore the registrant must submit efficacy data demonstrating that the product is efficacious against those specific pathogens that are pathogenic to humans. Specifically data should be submitted for the following microorganisms:

BACTERIA:

Streptococcus pyogenes
Campylobacter plyoridas
Klebiella pneumoniae
Escherichia coli
Salmonella typhimurium
Salmonella choleraesuis
Pseudomonas aeruginosa
Staphylococcus aureus
Staphylococcus epidermidis

VIRUSES:

Newscastle Disease
Infectious Bronchitis
Infectious Bursal Disease


FUNGI:

Candida albicans

2. The "blue bean sheet" package contained labeling prints for the product: VIRKON E (EPA Reg. No. 624321-12281); the proposed labeling language for the product VIRKON S includes some language that mentions the product VIRKON E. Please see the last page of the proposed labeling for VIRKON S.

3. Proposed claims such as "Clostridium spp, Leptospira spp, Campylobacter ssp" are unacceptable, the specific bacteria must be mentioned.

Note to File:
All of these (item)
claims were on
the last accepted
label. Therefore, no
data are required
at this time. We'll
have to request it
at reregistration.

(A) 	United States Environmental Protection Agency Office of Pesticide Programs (H7505C) Washington, DC 20460	<input type="checkbox"/> Registration	OPP Identifier Number 191019
		<input checked="" type="checkbox"/> Amendment	
Application for Pesticide:		<input type="checkbox"/> Other	

Section I

1. Company/Product Number 62432	2. EPA Product Manager Ms. Ruth G. Douglas	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Virkon S	PM# 32	
5. Name and Address of Applicant (Include ZIP Code) Antec International Ltd Chilton Industrial Estate Sudbury, Suffolk CO10 6XD ENGLAND <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____

Section II

<input checked="" type="checkbox"/> Amendment - Explain below	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Submission of Master EPA Label update for swine and equine species.

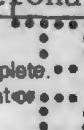
Final printed labels (5 each) for swine and equine species.

Identification of Antec International Ltd as basic registrant as revised on Master EPA Label.

Section III

1. Material This Product Will Be Packaged In:			
Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
* Certification must be submitted.			
If "Yes," Unit Package wgt.		No. per container	
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) of Retail Container 2.5 kg, 5.0 kg, 25 kg 35 grams, 50 grams	
5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product		6. Manner In Which Label Is Affixed To Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled <input checked="" type="checkbox"/> Other (Pressure Sensitive)	

Section IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Alan R. Wagner, D.V.M., M.S.	Title Manager, Regulatory Affairs Agent for Antec International Ltd	Telephone No. (Include Area Code) 305/553-9017
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment both under applicable law.		6. Date Application Received (Stamp) 
2. Signature Alan R. Wagner D.V.M., M.S.	3. Title Manager, Regulatory Affairs Agent for Antec International Ltd	
4. Typed Name Alan R. Wagner, D.V.M., M.S.	5. Date June 24, 1994	

PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

PAPERWORK REDUCTION ACT NOTICE: Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503.

INSTRUCTIONS: This form is to be used for all applications for new registration, end use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

1. Certification with Respect to Citation of Data (EPA Form 8570-29). [If not exempted by 40 CFR 152.81 (b) (4)];
2. Confidential Statement of Formula (EPA Form 8570-4);
3. Formulator's Exemption Statement (EPA Form 8570-27);
4. Five copies of draft labeling;
5. Three copies of any data submitted;
6. Authorization letter where applicable;
7. Metrics where applicable.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper or a mockup of the proposed label. If prepared as a mockup, it should be constructed in such a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission.

Submission of Data - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

SPECIFIC INSTRUCTIONS: Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended registration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.

Block A - Check the appropriate action for which you are submitting this form.

SECTION I - This section must be completed, as applicable, for all registration actions.

1. **Company/Product Number** - Insert your Company Number, if one has been assigned by EPA. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
2. **EPA Product Manager** - If known, fill in the name and PM number of the EPA Product Manager.
3. **Proposed Classification** - Specify the proposed classification of this product.
4. **Product Name** - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
5. **Name and Address of Applicant** - The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
6. **Expedited Review** - FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

SECTION II - This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA-registered product. This section is not to be used for a new application for registration.

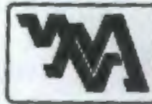
1. **Subject of submission** - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; general label revision of use directions." Attach a separate page if additional space is needed.

SECTION III (Packaging and Container Information) - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

1. **Type of Packaging** - Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
2. **Type of Retail Container** - Indicate type of container in which product will be marketed.
3. **Location of Use Directions** - Specify the net contents of all retail containers for your product.
4. **Size(s) of Retail Container** - Specify the net contents of all retail containers for your product.
5. **Location of Use Directions** - Indicate the location of the use directions for your product.
6. **Manner in which label is affixed to product** - Indicate the method product label is attached to retail container.

SECTION IV (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me-too," reregistration, etc.

- 1-5. Self-explanatory.
6. EPA Use Only.



MICROTEC
ANIMAL NUTRITION, INC.

301 Baybrook Street, Thomasville, Ga. 31792

January 4, 1994

Susan T. Lewis
Branch Chief
Room 229, E.P.A.
Office of Pesticide Programs
1921 Jefferson Davis Drive
Arlington, VA 22202

Dear Ms. Lewis:

Effective January 1, 1994 a new regulatory agent will represent Antec International Ltd., at E.P.A. Antec International manufactures Virkon S, E.P.A. Reg. No. 62431-1.

The name of the agent is Dr. Alan R. Wagner. His title and address follow:

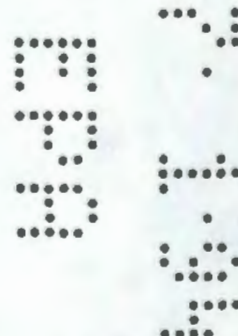
Alan R. Wagner, D.V.M., M.S.
Manager, Regulatory Affairs
4302 S.W. 147th Place
Miami, FL 33185
Phone 305/553-9017

Please communicate with Dr. Wagner on all E.P.A. matters concerning Virkon S and Antec International, Ltd.

Sincerely,

H.J. Van Veen
President
MICROTEC, INC.
U.S. Agents for Antec International, Ltd.

cc: R. Auchincloss, Antec International, Ltd.
Dr. Alan R. Wagner



W

DR. ALAN R. WAGNER
Regulatory Affairs and Technical Services

L

Private Consultation

4302 S.W. 147th Place
Miami, Florida 33185

(305) 553-9017

June 24, 1994

Ms. Ruth G. Douglas (PM32)
Antimicrobial Program Branch
Registration Division (7505C)
U.S. Environmental Protection Agency
401 M Street S.W.
Washington, D.C. 20460

Subject: Virkon S (EPA Reg. # 62432)

Dear Ms. Douglas:

Please find "Application For Pesticide Amendment" updating our EPA Approved Master Label that you discussed with me during our recent meeting in Washington, D.C. on June 14, 1994. We have included on the Master EPA Approved Label that you presented to me, the swine and equine specie claim accompanied by printed labels (5 each) identifying efficacy claims for microbial organisms as listed.

Also, in conformance with our discussions, we have identified ANTEC INTERNATIONAL LTD, Windham Road, Chilton Industrial Estates, Sudbury Suffolk CO10 6XD, England as the basic registrant identified on the Master EPA Approved Label. This submission does not modify label requirements for DIRECTIONS FOR USE; PRECAUTIONARY STATEMENTS; OR STORAGE AND DISPOSAL as approved on the Master EPA Label.

I certainly appreciated the opportunity to meet with you, Ms. Douglas, in my role as Country Agent USA for Antec International Ltd and to review label submissions and other pertinent Antec data that has been submitted to your office.

We will be anxious for your review and approval of the label submissions as we discussed, Ms. Douglas, so the labels can be released for the product package. If you should have any questions regarding the submission please call me at 305/553-9017. Enclosed, as per your request, is a copy of the letter appointing me as regulatory agent for Antec International Ltd.

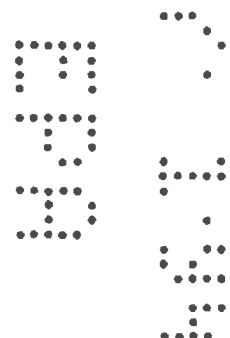
Again, thank you for your excellent assistance and the courtesy extended to me and I shall be looking forward to our next meeting.

Sincerely,

Alan R. Wagner
Alan R. Wagner, D.V.M., M.S.
Manager, Regulatory Affairs
Agent for Antec International Ltd.

ARW/mw

Attachments



62432-1

2.

AMENDMENT

191019

FAST TRACK • APPLICATION FOR AMENDMENT			
<u>WITH DATA</u>	Init.	Date	<u>NO DATA</u>
			Init. Date
FEU	_____	_____	FEU <u>J.W. 7-8-94</u>
SIG (DATA)	_____	_____	<u>32</u> PM _____
FEU	_____	_____	
PM	_____	_____	

REGULAR APPLICATION FOR AMENDMENT			
<u>WITH DATA</u>	Init.	Date	<u>NO DATA</u>
			Init. Date
FEU	_____	_____	FEU _____
SIG (DATA)	_____	_____	PM _____
PM	_____	_____	

- Front End Processing determined this application qualifies for fast track review based on registrants claim of "me-too". No screen for substantial similarity is made by the Front End.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

07/11/94

ALAN WAGNER, D.V.M., M.S.
DR ALAN WAGNER, DVM, MS
4302 SW 147 PLACE
MIAMI FL 33185

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

PRODUCT NAME: VIRKON S
COMPANY NAME: ANTEC INTERNATIONAL LTD.
OPP IDENTIFICATION NUMBER: 191019
EPA REGISTRATION NUMBER: 62432-1
EPA RECEIPT DATE: 07/01/94

SUBJECT: RECEIPT OF AMENDMENT

DEAR REGISTRANT:

The Office of Pesticide Programs has received your application for an amendment and it has passed an administrative screen for completeness.

During the initial screen we determined that the application qualifies for fast track review. The package will now be forwarded to the Product Manager for review to determine its acceptability.

If you have any questions, please contact Ruth Douglas, Product Manager 32, at (703)-305-7964.

Sincerely,

J. Wrice

Front End Processing Staff
Information Services Branch
Program Management and Support Division



Recycled/Recyclable
Printed with Soy/Canola Ink on paper that
contains at least 50% recycled fiber

Reviewer ID DE MESME
Submission No. 5483257
Data Package No. _____

CODING FORM FOR APPLICATIONS FOR REGISTRATION/AMENDMENTS

File Symbol/Reg. No. 62437-1 PM 32 Action Code 300

10 Descriptor (Amend/Resubmissions only) Final label

5 Intrastate Call-in ☐ (Y) Yes ☐ (N) No 15 Child-resistant Packaging ☐ (C) Certification ☐ (S) Service Person

20 Registration Type: ☐ (1) Conditional ☐ (2) Unconditional ☐ (R) Non-residential Use Only ☐ (N) Not-Applicable

25 Proposed Classification: ☐ (R) Restricted ☐ (G) General 30 Final Classification: ☐ (R) Restricted ☐ (N) Not Classified

35 Date on Application: 01/22/95 04 EPA Received Date: 01/22/95 40 Date Received by PM: 01/30/95
MO DAY YR MO DAY YR MO DAY YR

80 Method of Support: ☐ (1) Cite-All ☐ (6) Owner Submission ☐ (4) Not Applicable ☐ (7) Total Submission ☐ (5) Not Submitted ☐ (8) Selective Method

Reviewers Requested:	DATE SENT	DUE DATE	DATE RETURNED	RESPONSE CODE	RESPONSE DATE
CH					
EF					
PL					
DEB					
NDEB					
TB					
EEB					
EFGB					

115 FINAL Response ACTION Code 32 120 Response 01/30/95
Per 82-2 MO DAY YR
75-DAY RESPONSE DUE DATE: ☐ (Y) Yes ☐ (N) No

DR. ALAN R. WAGNER
Regulatory Affairs and Technical Services

Private Consultant
Clinical Investigations

2304 Anhinga Drive
Kissimmee, Florida 34743

Ph: 407/344-9803
Fax: 407/344-9980

February 21, 1995

Ms. Ruth G. Douglas (PM32)
Antimicrobial Program Branch
Registration Division (7505C)
U.S. Environmental Protection Agency
401 M Street S.W.
Washington, D.C. 20460

Subject: VirKon S and VirKon E (EPA Reg. # 62432-1)
 Submittance of Final Printed Labels

Dear Ms. Douglas:

In accordance with your letter of December 1, 1994, please find enclosed final printed labels (5) for products identified as VirKon S and VirKon E.

Thank you Ms. Douglas for your prompt review of our application and informing us of the acceptability of the submission. I also appreciate the assistance and courtesy extended to me and I shall be looking forward to our next meeting in Washington, D.C.

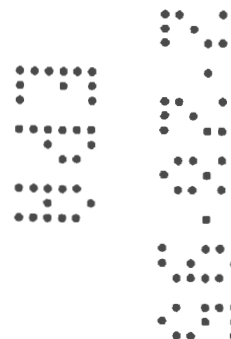
Sincerely,


Alan R. Wagner

Alan R. Wagner, D.V.M., M.S.
Agent for Antec International Ltd.

ARW/mw

Enclosures



(A) 	United States Environmental Protection Agency Office of Pesticide Programs (H7505C) Washington, DC 20460	<input type="checkbox"/> Registration <input type="checkbox"/> Amendment <input checked="" type="checkbox"/> Other	OPP Identifier Number 191009
	Application for Pesticide:		

Section I

1. Company/Product Number 62432-1	2. EPA Product Manager Ms. Ruth G. Douglas	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) VIRKON S	PM# 32	
5. Name and Address of Applicant (Include ZIP Code) Antec International Ltd. Chilton Industrial Estate Sudbury, Suffolk CO10 6XD ENGLAND <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____

Section II

<input type="checkbox"/> Amendment - Explain below	<input checked="" type="checkbox"/> Final printed labels in response to Agency letter dated December 1, 1995
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

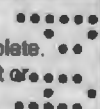
Submittance of five (5) final printed labels for:

- VIRKON S
- VIRKON E

Section III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input type="checkbox"/> Metal	<input checked="" type="checkbox"/> Plastic
	If "Yes," Unit Package wgt.	No. per container	If "Yes," Package wgt.	<input type="checkbox"/> Glass	<input type="checkbox"/> Paper
				<input type="checkbox"/> Other (Specify) _____	
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container			4. Size(s) of Retail Container 2.5 Kg., 5.0 Kg., 2.5 Kg., 35 grams, 50 grams	5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner In Which Label Is Affixed To Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			<input checked="" type="checkbox"/> Other (Pressure Sensitive)		

Section IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Alan R. Wagner, D.V.M., M.S.	Title Agent for Antec International Ltd.	Telephone No. (Include Area Code) 800 828 8288
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped) 
2. Signature Alan R. Wagner, D.V.M., M.S.	3. Title Agent for Antec International Ltd.	
4. Typed Name Alan R. Wagner, D.V.M., M.S.	5. Date February 21, 1995	

PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

PAPERWORK REDUCTION ACT NOTICE: Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503.

INSTRUCTIONS: This form is to be used for all applications for new registration, end use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

1. Certification with Respect to Citation of Data (EPA Form 8570-29). [If not exempted by 40 CFR 152.81 (b) (4)];
2. Confidential Statement of Formula (EPA Form 8570-4);
3. Formulator's Exemption Statement (EPA Form 8570-27);
4. Five copies of draft labeling;
5. Three copies of any data submitted;
6. Authorization letter where applicable;
7. Matrices where applicable.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper or a mockup of the proposed label. If prepared as a mockup, it should be constructed in such a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission.

Submission of Data - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

SPECIFIC INSTRUCTIONS: Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended registration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.

Block A - Check the appropriate action for which you are submitting this form.

SECTION I - This section must be completed, as applicable, for all registration actions.

1. **Company/Product Number** - Insert your Company Number, if one has been assigned by EPA. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
2. **EPA Product Manager** - If known, fill in the name and PM number of the EPA Product Manager.
3. **Proposed Classification** - Specify the proposed classification of this product.
4. **Product Name** - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
5. **Name and Address of Applicant** - The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
6. **Expedited Review** - FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

SECTION II - This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA-registered product. This section is not to be used for a new application for registration.

1. **Subject of submission** - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; general label revision of use directions." Attach a separate page if additional space is needed.

SECTION III (Packaging and Container Information) - This section must be completed for all applications submitted in connection with new registration or applicable amendments.

1. **Type of Packaging** - Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
2. **Type of Retail Container** - Indicate type of container in which product will be marketed.
3. **Location of Net Contents** - Specify the net contents of all retail containers for your product.
4. **Size(s) of Retail Containers** - Specify the net contents of all retail containers for your product.
5. **Location of Use Directions** - Indicate the location of the use directions for your product.
6. **Manner in which label is affixed to product** - Indicate the method product label is attached to retail container.

SECTION IV (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me-too," reregistration, etc.

- 1-5. Self-explanatory.
6. EPA Use Only.

VirKon S

BROAD SPECTRUM DISINFECTANT
VIRKON S is effective against numerous microorganisms affecting animals: viruses, Gram positive and Gram negative bacteria, fungi (molds and yeasts), and Mycoplasma. Efficacy was determined in the presence of hard water and organic material.

DIRECTION FOR USE

Federal law prohibits use of this product in a manner inconsistent with its labeling. This powder formula is easily diluted for use in manual or machine operations.

POULTRY PRODUCTION/RATITE PRODUCTION

VIRKON S is recommended for use in hatcheries, in chicken houses, and in Ratite production.

CONTROLS: Viruses of Newcastle Disease, Infectious Bronchitis, Infectious Bursal Disease, Laryngotracheitis, Avian Influenza, Marek's Disease and Egg Drop Syndrome. Fungi: *Aspergillus flavus*, *Aspergillus fumigatus* and *Candida albicans*. Bacteria: *Streptococcus pyogenes*, *Campylobacter pyloridis*, *Escherichia coli*, *Salmonella typhimurium*, *Salmonella choleraesuis*, *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Staphylococcus epidermidis*, *Mycoplasma gallisepticum*, *Necrotic enteritis*.

HATCHERIES: VIRKON S at 1% solution is generally suitable for cleaning and disinfecting hatchery, setters, evaporative coolers, humidifying systems, ceiling fans, chicken houses, transfer trucks, trays, and plastic chick boxes (use 2% solution for Mycoplasma and *Aspergillus* and 3% solution for *Aspergillus fumigatus*).

VIRKON S is recommended for use in logging (wet misting) operations as an adjunct either preceding or following regular cleaning and disinfecting procedures. VIRKON S at 1-2% solution is suitable. Fog (wet mist) until the area is moist using automatic wet foggers according to manufacturer's use directions.

VIRKON S passes the AOAC germicidal and detergent sanitizer test at a concentration of 0.5% (1:200) in the presence of 200 ppm hard water.

Continued on reverse side.

durvet



VirKon S

BROAD SPECTRUM DISINFECTANT
For Use in Cleaning and Disinfecting Industrial Animal and Agricultural Facilities
EFFECTIVE AGAINST SWINE & POULTRY PATHOGENS

BACTERIA	VIRUSES OF	FUNGI
<i>Streptococcus pyogenes</i> <i>Campylobacter pyloridis</i> <i>Klebsiella pneumoniae</i> <i>Escherichia coli</i> <i>Salmonella typhimurium</i> <i>Salmonella choleraesuis</i> <i>Pseudomonas aeruginosa</i> <i>Staphylococcus aureus</i> <i>Staphylococcus epidermidis</i> <i>Mycoplasma gallisepticum</i> <i>Clostridium</i> spp. <i>Bordetella bronchiseptica</i> <i>Pasteurella multocida</i> <i>Campylobacter</i> spp. <i>Erysipelothrix rhusiopathiae</i> <i>Leptospira</i> spp. <i>Actinobacillus pleuropneumoniae</i> <i>Treponema hyodysenteriae</i>	Newcastle Disease Infectious Bronchitis Infectious Bursal Disease Avian Laryngotracheitis Avian Influenza Marek's Disease Egg Drop Syndrome Hog cholera Swine Influenza TGE Porcine parvovirus Rotaviral diarrhea Vesicular stomatitis Pseudorabies PRRS (Porcine Reproductive & Respiratory Syndrome)	<i>Aspergillus flavus</i> <i>Aspergillus fumigatus</i> <i>Candida albicans</i>

ACTIVE INGREDIENTS	
Potassium peroxymonosulfate	20.4%
Sodium Chloride	1.5%
INERT INGREDIENTS	
	78.1%
TOTAL	100.0%

Equivalent to 9.75% Available Chlorine

KEEP OUT OF REACH OF CHILDREN

DANGER:

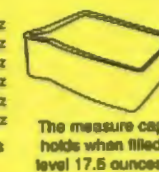
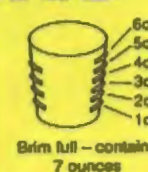
See Side Panel for Additional Precautions

5lbs
Net Weight

VirKon S

DILUTION CHART

Quantity of Final Solution American	1% Solution	2% Solution
1 gallon	1.3 ounces	2.7 ounces
10 gallons	13.4 ounces	26.7 ounces
50 gallons	66.8 ounces	133.5 ounces



For DISINFECTING use a rate of 7.5 gallons/1000 sq. ft.

For CLEANING AND DISINFECTING use a rate of 15 gallons/1000 sq. ft.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER

Corrosive. Causes skin burns and irreversible eye damage. Harmful if swallowed, absorbed through skin, or inhaled. Do not get in eyes, on skin, or on clothing. Wear protective clothing and rubber gloves. Avoid breathing dust. Wear goggles, face shield, or safety glasses. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

PRACTICAL TREATMENT

IF IN EYES: Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes. Get prompt medical attention.

IF ON SKIN: Wash with plenty of soap and water. Get medical attention if irritation persists.

IF INHALED: or symptoms of coughing, choking, or wheezing are troublesome, remove to fresh air and seek medical attention.

IF SWALLOWED: Drink promptly a large quantity of water. Avoid alcohol. Get immediate medical attention.

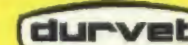
NOTICE OF PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

Distributed by



301 Baybrook Street, Thomasville, GA 31792

Manufactured for



Durvet Inc. Blue Springs, Missouri, 64015-1 800-821-5570
EPA Reg. No. 62432-1-12281. EPA Est. No. 62432-EN-001

VirKon is a registered trademark of and manufactured by
Antec International Limited U.S. Patent No. 4822512
Made in England by Antec International Limited



DIRECTIONS FOR USE CONTINUED

BROILER/BREEDER HOUSES:

Following removal of chickens, feed and water troughs, remove manure and litter and spray floor and side walls with VIRKON S at 1%. Thoroughly wash waterers and feeders with a 1% solution of VIRKON S (use 2% solution for Mycoplasma and *Aspergillus fumigatus*). After contact for ten minutes, rinse with potable water. Do not use to house poultry or employ equipment until the treatment has dried.

SWINE PRODUCTION

CONTROLS: Viruses of Hog Cholera, Porcine Parvo Disease, Vesicular Stomatitis, PRRS, Pseudorabies, Rotaviral Diarrhea, Swine Influenza, Foot and Mouth Disease and TGE. Bacteria of Arthritis, Meningitis, Atrophic Rhinitis, Pasteurellosis, Colibacillosis, Enteritis, Erysipelas, Leptospirosis, Mastitis, Necrotic Enteritis, Pleuropneumonia, Salmonellosis and Swine Dysentery. Fungi (molds and yeasts) *Aspergillus flavus*, *Aspergillus fumigatus* and *Candida albicans*.

VIRKON S is recommended for use in farrowing pens, weaner accommodation grower accommodation and finisher accommodation and processing plants: VIRKON S at 1% solution is generally suitable for cleaning and disinfecting (use 2% solution for Mycoplasma and *Aspergillus* and 3% solution for *Aspergillus fumigatus*).

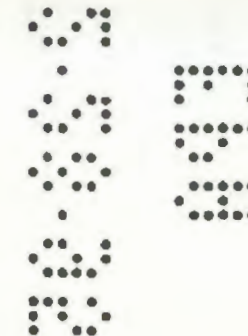
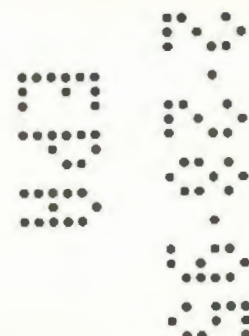
VIRKON S is recommended for use in logging (wet misting) operations or as an adjunct either preceding or following regular cleaning and disinfecting procedures. VIRKON S at 1-2% solution is suitable. Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions.

FOR AIR SANITIZING: Use VIRKON S at 1-2% solution. Fog the atmosphere until surfaces are moist. Allow at least 2 hours before entering area that has been fogged.


STORAGE & DISPOSAL: Store in a cool, dry place in tightly closed container. Keep out of reach of children. Always replace lid after use. Wash empty container thoroughly and dispose of in trash.

NOT REVIEWED

In Accordance with FR Notice 82-2,
Based on Draft Labeling Dated



2000



VirKon.E

ACTIVE INGREDIENTS	Potassium permanganate sulfate	20.4%
	Sodium chloride	1.5%
INERT INGREDIENTS		78.1%
TOTAL		100.0%

Manufactured by MICROTEC ANIMAL NUTRITION, INC. 301 Baybrook Blvd., Thorndale, IL 61092
Phone (912) 275-4182

BROAD SPECTRUM DISINFECTANT
VIOXON K is effective against numerous microorganisms affecting animals, humans, Gram positive and Gram negative bacteria, fungi (moulds and yeasts), and all protozoa. Efficacy was determined in the presence of hard soiled and organic material.

Polishing and deburring of all various components, usually and however on big "handmade" machines, barrels, shafts, gears, etc.

INSTRUCTIONS FOR USE

add the amounts of costs passed to our method of report users. Translating our results for 7 days:

11 months of minimum investment? (costs) 1000
 2 years of minimum investment? (costs) 1000

Produced from *penicillium* and *trichoderma* products (4) is another important source of antibiotics.

This product is not to be used for you if you are pregnant or nursing.

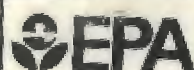
STREKON prevents the ACU's germination and development, without loss of virulence (100% at 1:1000) in the presence of 100 µg/ml of formalin.



45801-14159

195813

Approval expires 3-31-89.



U.S. ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PESTICIDE PROGRAMS (TS-767)
WASHINGTON, DC 20460

NOTICE OF SUPPLEMENTAL REGISTRATION OF DISTRIBUTOR

(Please read instructions before completing)

EPA REGISTRATION NO. OF PRODUCT	DISTRIBUTOR COMPANY NUMBER
1-778-91-9 6162432	63690-294
NAME AND ADDRESS OF BASIC REGISTRANT (print or type; include ZIP code)	
A. H. Robins Company 1405 Cummings Drive P. O. Box 26609 Richmond, VA 23261-6609	
NAME OF REGISTERED PRODUCT (basic product name accepted by EPA)	
VIRKON-S	
DISTRIBUTOR PRODUCT NAME	
VIRKON-S	
NAME AND ADDRESS OF DISTRIBUTOR (print or type; include ZIP code)	
AGRI-BIO CORPORATION 966 DORSEY ST., GAINESVILLE, GEORGIA 30501	
DISTRIBUTOR	
We intend to market under the Distributor Product Name and Number specified above, subject to the conditions specified on this form.	
SIGNATURE AND TITLE OF DISTRIBUTOR	DATE
H. J. Zacher, President	6 MAR 90
REGISTRANT	
It is requested that the Registration Record of this jacket include the Distributor Product specified above, subject to the conditions specified on this form.	
SIGNATURE AND TITLE OF REGISTRANT	DATE
Ronald L. Gilbert, District Field Manager P&D	March 7, 90

INSTRUCTIONS

After a registrant has obtained final registration for the basic product, the registrant may then supplementally register and distribute his/her product. One form must be submitted for each distributor brand and must be signed by the distributor involved. The form must state the basic registration number and the distributor company number.

If a registrant has a potential distributor who does not have a company number assigned, she/he should have the distributor apply, on letterhead stationery, to the Registration Division to have a number assigned prior to submitting a Distributor Notification to the Agency.

Notification forms must be submitted by the basic registrant. They must have the concurrence and signature of both the registrant and the distributor.

When submitting several forms for the same basic product, submitting them together will facilitate processing.

NOTE: DO NOT submit distributor product labels.

CONDITIONS

1. The distributor product must have the same composition as the basic registered product.
2. The distributor brand product must be manufactured and packaged by the same person who manufactures and packages the registered basic product.
3. The labeling for the distributor product must bear the same claims as the basic product, provided, however, that specific claims may be deleted if by doing so no other changes are necessary.
4. The product must remain in the manufacturer's unbroken container.
5. The label must bear the EPA registration number of the basic registered product, followed by a hyphen and the distributor's company number.
6. Distributor products must bear the name and address of the distributor qualified by such terms as "packed for . . ." "distributed by . . ."; or "sold by . . ." to show that the name is not that of the manufacturer.
7. All conditions of the basic registration apply equally to distributor brand products. It is the responsibility of the basic registrant to see that all distributor labeling is kept in compliance with requirements placed on the basic product.

RECEIVED BY EPA REGISTRATION DIVISION ON THE DATE STAMPED BELOW

3-31-90

EPA Form 8570-5 (Rev. 4-83) Previous editions are obsolete.

APPLICANT - Send only original to EPA - Retain copies

Reviewer ID

Pringle

Submission No.

5423189

Data Package No. _____

CODING FORM FOR APPLICATIONS FOR REGISTRATION/AMENDMENTS

File Symbol/Reg. No. 62438-1 PM 32Action Code 301☒ [10] Descriptor (Amend/Resubmissions only)Attach to 6/24/94 Amendment - (Resubmission)☒ [5] Intrastate Call-in ☐ (Y) Yes☒ [15] Child-resistant Packaging☐ (C) Certification☐ (N) No☐ (S) Service Person☒ [20] Registration Type:☒ (1) Conditional☐ (2) Unconditional☐ (R) Non-residential Use Only☐ (N) Not-Applicable☒ [25] Proposed Classification: ☒ [30] Final Classification:☐ (R) Restricted☐ (R) Restricted☐ (G) General☐ (N) Not Classified☒ [35] Date on Application:☒ [04] EPA Received Date:☒ [40] Date Received by PM0 8 2 9 9 4
MO DAY YR0 9 0 6 9 4
MO DAY YR0 9 1 3 9 4
MO DAY YR☒ [80] Method of Support:☐ (1) Cite-All☐ (6) Owner Submission☐ (4) Not Applicable☐ (7) Total Submission☐ (5) Not Submitted☐ (8) Selective Method

Reviewers Requested:

CH

EF

PL

DEB

NDEB

TB

EEB

EFCB

DATE
SENTDUE
DATEDATE
RETURNEDRESPONSE
CODERESPONSE
DATE

☒ [115] FINAL Response ACTION Code 17☐ [120] ResponseDEC 01 1994

MO DAY YR

75-DAY RESPONSE DUE DATE: ☐ (Y) Yes☐ (N) No

101

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

DEC 01 1994

Alan R. Wagner, D.V.M., M.S.
Agent for Antec International Ltd.
Regulatory Affairs and Technical Services
4302 S.W. 147th Place
Miami. FL 33185

SUBJECT: VIRKON S
EPA Registration No. 62432-1
Amendment Dated August 29, 1994

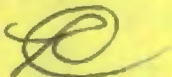
Dear Dr. Wagner:

This is in response to your amendment dated August 29, 1994 requesting to add Porcine Reproductive and Respiratory Syndrome (PRRS) viruses and the fungus *Aspergillus fumigatus* claims to your label. The amendment is acceptable and no further data is required since these claims are not related to human health.

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, is acceptable. Submit five copies of the finished label before you release the product for shipment bearing the amended labeling.

If you have any further questions, please contact Ms. Barbara Pringle at (703)305-6484.

Sincerely,



Ruth G. Douglas
Product Manager 32
Antimicrobial Program Branch
Registration Division(7505C)

CONCURRENCES

SYMBOL	7505C					
SURNAME	Pringle					
DATE	11-29					

EQUINE BACTERIA

Clostridial diarrhea
Salmonellosis
Enteric Colibacillosis
Fistulous Withers (Poll Evil)
Contagious Equine Metritis (CEM)
Strangles, Glanders

EQUINE VIRUSES

African Horse Sickness
Equine Viral Arteritis (Pink Eye)
Coital Exanthema
Myeloencephalopathy
Rhinopneumonitis

Equine Contagious Abortion
Equine Papillomatosis
Equine Infectious Anemia (Swamp Fever)
Adenovirus Pneumonia
Equine Influenza (The Cough)
Rhinitis

EQUINE FUNGUS

Dermatophytosis (Ringworm)
Dermatophytosis (Mud Fever)

**Antec
International**

V

(Virkon logo)

VIRKON® S BROAD SPECTRUM DISINFECTANT

For Use in Cleaning and Disinfecting Industrial
Animal and Agricultural Facilities

EFFECTIVE AGAINST:

BACTERIA

Streptococcus pyogenes
Campylobacter pyloridis
Klebsiella pneumoniae
Escherichia coli
Salmonella typhimurium
Salmonella choleraesuis
Pseudomonas aeruginosa
Staphylococcus aureus
Staphylococcus epidermidis
Mycoplasma gallisepticum
Clostridium spp

VIRUSES OF

Newcastle Disease
Infectious Bronchitis
Infectious Bursal Disease

Avian Laryngotracheitis
Avian Influenza
Marek's Disease
Egg Drop Syndrome

FUNGI

Aspergillus flavus
Aspergillus fumigatus
Candida albicans

ACTIVE INGREDIENTS

Potassium peroxymonosulfate..... 20.4%
Sodium Chloride..... 1.5%
INERT INGREDIENTS..... 78.1%
TOTAL..... 100.0%

Equivalent to 9.75% Available Chlorine

**KEEP OUT OF REACH OF CHILDREN
DANGER:**

See Back Panel for Additional Precautions

11 lbs (5Kg) Net Weight

ANTEC INTERNATIONAL LTD
Windham Road, Chilton Industrial Estates
Sudbury Suffolk CO10 6XD, England
Tel: (0787) 77303 Telx: 987495 Fax: (0787) 310846

SWINE BACTERIA

Bacteria: Bordetella bronchiseptica,
Pasteurella multocida, Campylobacter
spp, Erysipelothrix rhusiopathiae,
Leptospira spp, Actinobacillus
pleuropneumoniae, Treponema
hyodysenteriae.

SWINE VIRUSES: Hog cholera,
Swine influenza, TGE, Porcine
parvovirus, Rotaviral diarrhea,
Vesicular stomatitis, Pseudorabies,
Porcine Reproductive and
Respiratory Syndrome (PRRS).

ACCEPTED
with COMMENTS
in EPA Letter Dated

DEC 01 1994

Under the Federal Insecticide,
Fungicide, and Rodenticide Act
as amended, for the pesticide
registered under EPA Reg. No.

62432-1



VIRKON S is a registered trademark of and manufactured by Antec International Limited

U.S. Patent No. 4822512

SIDE PANEL

BROAD SPECTRUM DISINFECTANT

VIRKON S is effective against numerous microorganisms affecting animals: viruses, gram positive and gram negative bacteria, fungi (molds and yeasts), and mycoplasma. Efficacy was determined in the presence of hard water and organic material.

CONTROLS

Viruses of Newcastle Disease, Infectious Bronchitis, Infectious Bursal Disease, Avian Laryngotracheitis, and Avian Influenza. **Fungi** (molds and yeasts - *Aspergillus flavus*, *Aspergillus fumigatus* and *Candida albicans*). **Bacteria** - *Streptococcus pyogenes*, *Campylobacter pyloridis*, *Klebsiella pneumoniae*, *Escherichia coli*, *Salmonella typhimurium*, *Salmonella choleraesuis*, *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Staphylococcus epidermidis*, *Mycoplasma gallisepticum*.

DIRECTIONS FOR USE

Federal law prohibits use of this product in a manner inconsistent with its labeling.

This powder formula is easily diluted for use in manual or machine operations.

POULTRY PRODUCTION/RATITE PRODUCTION

VIRKON S is recommended for use in hatcheries, chicken houses, Ratite production and processing plants.

HATCHERIES: **VIRKON S** at 1% solution is generally suitable for cleaning and disinfecting hatchers, setters, evaporative coolers, humidifying systems, ceiling fans, chicken houses, transfer trucks, trays, and plastic chick boxes (use 2% solution for *Mycoplasma*, *Aspergillus flavus* and *Aspergillus fumigatus*). **VIRKON S** is recommended for use in fogging (wet misting) operations as an adjunct either preceding or following regular cleaning and disinfecting procedures. **VIRKON S** at 1-2% solution is suitable. Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions.

BROILER/BREEDER HOUSES: Following removal of chickens, feed, and water troughs, remove manure and litter and spray floors and side walls with **VIRKON S** at 1% solution. Thoroughly wash waterers and feeders with a 1% solution of **VIRKON S** (use 2% solution for *Mycoplasma*, *Aspergillus flavus* and *Aspergillus fumigatus*). After contact for 10 minutes, rinse with potable water. Do not use to house poultry or employ equipment until treatment has dried.

FOR AIR SANITIZING: Use **VIRKON S** at 1-2% solution. Fog the atmosphere until surfaces are moist. Allow at least 2 hours before entering area that has been fogged.

PROCESSING PLANTS: For disinfecting and cleaning walls, ceilings, and floors spray at a dilution of 1%.

SIDE PANEL CONTINUED

SWINE PRODUCTION

CONTROLS: Viruses of Hog Cholera, Porcine Parvo Disease, Vesicular Stomatitis, Pseudorabies, Porcine Reproductive and Respiratory Syndrome (PRRS) Rotoviral Diarrhea, Swine influenza, Foot and Mouth Disease and TGE. Bacteria of Arthritis, Meningitis, Atrophic Rhinitis, Pasteurellosis, Colibacillosis, Enteritis, Erysipelas, Leptospirosis, Mastitis, Necrotic Enteritis, Pleuropneumonia, Salmonellosis and Swine Dysentery. Fungi (molds and yeasts) *Aspergillus flavus*, *Aspergillus fumigatus* and *Candida albicans*.

VIRKON S is recommended for use in farrowing pens, weaner accommodation, grower accommodation and finisher accommodation and processing plants. VIRKON S at 1% solution is generally suitable for cleansing and disinfecting (use 2% solution for *Mycoplasma*, *Aspergillus flavus* and *Aspergillus fumigatus*).

VIRKON S is recommended for use in fogging (wet misting) operations or as an adjunct either preceding or following regular cleaning and disinfecting procedures. VIRKON S at 1-2% solution is suitable. Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions.

EQUINE PRODUCTION

APPLICATIONS

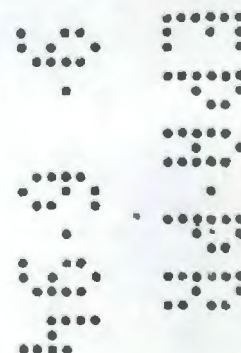
For cleaning and disinfection of all surfaces, equipment, utensils and instruments in Veterinary practices, kennels, stables, catteries, etc.

DIRECTIONS FOR USE

Add the contents of one sachet to one gallon of warm water. In cases of parvovirus challenge, add the contents of two sachets to one gallon of water. Solutions are stable for 7 days. Do not soak metal objects for long periods - 10 minutes is maximum necessary contact time.

CONTROLS

Viruses of African Horse Sickness, Equine Viral Arteritis (Pink Eye), Coital Exanthema, Myeloencephalopathy, Rhinopneumonitis, Equine Contagious Abortion, Equine Papillomatosis, Equine Infectious Anaemia (Swamp Fever) Adenovirus Pneumonia, Equine Influenza (The Cough) and Rhinitis, Bacterial; Clostridial Diarrhea, Salmonellosis, Enteric Colibacillosis, Fistulous Withers (Poll Evil), Contagious Equine Metritis (CEM) Strangles and Glanders. Fungi; Dermatophytosis (Ringworm) and Dermatophylosis (Mud Fever).



BACK PANEL

VIRKON® S

DILUTION CHART

<u>Quantity of Final Solution</u>	<u>1% Solution</u>	<u>2% Solution</u>
American		
1 gallon	1.3 ounces	2.7 ounces
10 gallons	13.4 ounces	26.7 ounces
50 gallons	68.8 ounces	133.5 ounces
Metric		
10 liters	100 grams	200 grams
50 liters	500 grams	1000 grams
200 liters	2 kgs	4 kgs

125g
100g
75g
50g

6oz
5oz
4 oz
3oz
2oz
1oz

Brim full - contains
200g or 7 ounces

The measure cap holds when
filled level 500g or 17.5 ounces.

For DISINFECTING use a rate of 7.5 gallons/1000 sq. ft.

For CLEANING AND DISINFECTING use a rate of 15 gallons/1000 sq. ft.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER

Corrosive. Causes skin burns and irreversible eye damage. Harmful if swallowed, absorbed through skin, or inhaled. Do not get in eyes, on skin, or on clothing. Wear protective clothing and rubber gloves. Avoid breathing dust. Wear goggles, face shield, or safety glasses. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

PRACTICAL TREATMENT

IF IN EYES: Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes. Get prompt medical attention.

IF ON SKIN: Wash with plenty of soap and water. Get medical attention if irritation persists.

IF INHALED or symptoms of coughing, choking, or wheezing are troublesome, remove to fresh air and seek medical attention.

IF SWALLOWED: Drink promptly a large quantity of water. Avoid alcohol. Get immediate medical attention.

NOTICE OF PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

STORAGE AND DISPOSAL - Store in a cool, dry place in tightly closed container away from children. Always replace lid after use. Wash empty container thoroughly and dispose of in trash.

ANTEC INTERNATIONAL LTD
Windham Road, Chilton Industrial Estates
Sudbury Suffolk CO10 6XD, England
Tel: (0787) 77305 Telex: 987495 Fax: (0787) 310846

EPA Reg. No. 62432-1

EPA Est. No. 62432-EN-001

durvet

ACCEPTED
with COMMENTS
in EPA Letter Dated:

DEC 01 1994

Under the Federal Insecticide,
Fungicide, and Rodenticide Act
as amended, for the pesticide
registered under EPA Reg. No.
62432-1



VirKon® S

BROAD SPECTRUM DISINFECTANT

For Use in Cleaning and Disinfecting Industrial
Animal and Agricultural Facilities

EFFECTIVE AGAINST

BACTERIA	VIRUSES OF	FUNGI
<i>Streptococcus pyogenes</i> <i>Campylobacter pyloridis</i> <i>Klebsiella pneumoniae</i> <i>Escherichia coli</i> <i>Salmonella typhimurium</i> <i>Salmonella choleraesuis</i> <i>Pseudomonas aeruginosa</i> <i>Staphylococcus aureus</i> <i>Staphylococcus epidermidis</i> <i>Mycoplasma gallisepticum</i> <i>Clostridium spp</i>	Newcastle Disease Infectious Bronchitis Infectious Bursal Disease Avian Laryngotracheitis Avian Influenza Marek's Disease Egg Drop Syndrome	<i>Aspergillus flavus</i> <i>Candida albicans</i> <i>Aspergillus fumigatus</i>

ACTIVE INGREDIENTS

Potassium peroxymonosulfate 20.4%
 Sodium Chloride 1.5%
 INERT INGREDIENTS 78.1%
 TOTAL 100.0%

Equivalent to 9.75% Available Chlorine

**KEEP OUT OF REACH OF CHILDREN
DANGER:**

See Back Panel for Additional Precautions

10lbs Net Weight

Distributed By:



301 Baybrook Street, Thomasville, GA 31792

Made in England by Antec International Limited

VIRKON S is a registered trademark of and manufactured by
Antec International Limited U.S. Patent No. 4,822,512



BROAD SPECTRUM DISINFECTANT

VIRKON S is effective against numerous microorganisms affecting animals:
 viruses, Gram positive and Gram negative bacteria, fungi (molds and yeasts), and
 Mycoplasma. Efficacy was determined in the presence of hard water and organic
 material.

DIRECTION FOR USE

Federal law prohibits use of this product in a manner inconsistent with its
 labeling.

This powder formula is easily diluted for use in manual or machine operations.

POULTRY PRODUCTION/RATITE PRODUCTION

VIRKON S is recommended for use in hatcheries, in chicken houses and in
 Ratite production.

CONTROLS: Viruses of Newcastle Disease, Infectious Bronchitis, Infectious
 Bursal Disease, Laryngotracheitis, Avian Influenza, Marek's Disease and Egg
 Drop Syndrome. Fungi: *Aspergillus flavus* and *Candida albicans*. Bacteria:
Streptococcus pyogenes, *Campylobacter pyloridis*, Infectious Bronchitis,
Klebsiella pneumoniae, *Escherichia coli*, *Salmonella typhimurium*, *Salmonella*
choleraesuis, *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Staphylococcus*
epidermidis, *Mycoplasma gallisepticum*, Necrotic enteritis.

HATCHERIES: VIRKON S at 1% solution is generally suitable for cleaning and
 disinfecting hatcheries, setters, evaporative coolers, humidifying systems, cooling
 fans, chicken houses, transfer trucks, trays, and plastic chick boxes (use 2%
 solution for *Mycoplasma* and *Aspergillus flavus*).

VIRKON S is recommended for use in logging (wet misting) operations as an
 adjunct either preceding or following regular cleaning and disinfecting procedures.
 VIRKON S at 1-2% solution is suitable. Fog (wet mist) until the area is moist using
 automatic wet loggers according to manufacturer's use directions.

BROILER/BREEDER HOUSES: Following removal of chickens, feed and water
 troughs, remove manure and litter and spray floors and side walls with VIRKON S
 at 1%. Thoroughly wash waterers and feeders with a 1% solution of VIRKON S
 (use 2% solution for *Mycoplasma* and *Aspergillus flavus*). Do not use to house
 poultry or employ equipment until the treatment has dried.

SWINE PRODUCTION

CONTROLS: Viruses of African Swine Fever, Hog Cholera, Porcine Parvovirus, Disease,
 Vesicular Stomatitis (PRRS), Pseudorabies, Rotaviral Diarrhea, Swine Influenza,
 Foot and Mouth Disease and TGE. Bacteria of Arthritis, Meningitis, *Salmonella*
 Rhinitis, Pasteurellosis, Colibacillosis, Enteritis, *Erysipelas*, Leptospirosis, Mastitis,
 Necrotic Enteritis, Pleuropneumonia, Salmonellosis and Swine Dysentery. Fungi
 (molds and yeasts) *Aspergillus flavus* and *Candida albicans*.

VIRKON is recommended for use in Farrowing pens, weaner accommodation
 grower accommodation and finisher accommodation and processing plants: VIRKON
 S at 1% solution is generally suitable for cleaning and disinfecting (use 2%
 solution for *Mycoplasma* and *Aspergillus flavus*).

VIRKON S is recommended for use in logging (wet misting) operations as an
 adjunct either preceding or following regular cleaning and disinfecting procedures.
 VIRKON S at 1-2% solution is suitable. Fog (wet mist) until the area is moist using
 automatic loggers according to manufacturer's use directions.

FOR AIR SANITIZING: Use VIRKON S at 1-2% solution. Fog the atmosphere
 until surfaces are moist. Allow at least 2 hours before entering area that has been
 logged.

STORAGE & DISPOSAL: Store in a cool, dry place in tightly closed container.
 Always replace lid after use. Wash empty container thoroughly and dispose of in
 trash.

Ratite

*Aspergillus
fumigatus*

and
*Aspergillus
fumigatus*

and
*Aspergillus
fumigatus*

After contact
time of 10
minutes, rinse
with potable
water.

Porcine
Respiratory
and Repro-
ductive
Syndrome

Atrophic

Erysipelas

and
*Aspergillus
fumigatus*

durvet



VirKon® S

BROAD SPECTRUM DISINFECTANT

For Use in Cleaning and Disinfecting Industrial
Animal and Agricultural Facilities

EFFECTIVE AGAINST

BACTERIA	VIRUSES OF	FUNGI
Streptococcus pyogenes	Hog cholera	Aspergillus flavus
Staphylococcus aureus	Swine influenza	Candida albicans
Klebsiella pneumoniae	TGE	
Escherichia coli	Blue-eye	Aspergillus fumigatus
Salmonella typhimurium	Porcine parvovirus	
Salmonella choleraesuis	Rotaviral diarrhoea	
Pseudomonas aeruginosa	Vesicular stomatitis	
Staphylococcus epidermidis	Pseudorabies	
Mycoplasma spp	PRRS (Porcine	
Bordetella bronchiseptica	Reproductive	
Pasteurella multocida	and Respiratory	
Campylobacter spp	Syndrome)	
Erysipelothrix rhusiopathiae		
Leptospira spp		
Clostridium spp		
Actinobacillus pleuropneumoniae		
Treponema hyodysenteriae		

**KEEP OUT OF REACH OF CHILDREN
DANGER:**

See Back Panel for Additional Precautions

10lbs Net Weight

Distributed By:



301 Baybrook Street, Thomasville, GA 31792

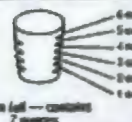
Made in England by Antec International Limited

VIRKON S is a registered trademark of and manufactured by
Antec International Limited U.S. Patent No. 4822512

VirKon® S

DILUTION CHART

Quantity of Final Solution	1% Solution	2% Solution
American		
1 gallon	1.3 ounces	2.7 ounces
10 gallons	13.4 ounces	26.7 ounces
50 gallons	66.8 ounces	133.5 ounces



Bucket full — contains
7 ounces



The measuring cup holds when
filled level 17.5 ounces.

For DISINFECTING use a rate of 7.5 gallons/1000 sq. ft.
For CLEANING AND DISINFECTING use a rate of 15 gallons/1000 sq. ft.

PRECAUTIONARY STATEMENTS

**HAZARDS TO HUMANS AND
DOMESTIC ANIMALS**

DANGER

Corrosive. Causes skin burns and irreversible eye damage. Harmful if swallowed, absorbed through skin, or inhaled. Do not get in eyes, on skin, or on clothing. Wear protective clothing and rubber gloves. Avoid breathing dust. Wear goggles, face shield, or safety glasses. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

PRACTICAL TREATMENT

IF IN EYES: Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes. Get prompt medical attention.

IF ON SKIN: Wash with plenty of soap and water. Get medical attention if irritation persists.

IF INHALED: or symptoms of coughing, choking, or wheezing are troublesome, remove to fresh air and seek medical attention.

IF SWALLOWED: Drink promptly a large quantity of water. Avoid alcohol. Get immediate medical attention.

NOTICE OF PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

durvet

Manufactured for

Durvet Inc. Blue Springs, Missouri, 64015-1-800-821-5570
EPA Reg. No. 62432-1-12281, EPA Est. No. 62432-EN-001

Made in England by Antec International Limited

EFFICACY EVALUATION AND TECHNICAL MANAGEMENT SECTION

EFFICACY REVIEW -I

ANTIMICROBIAL PROGRAM BRANCH

IN 9-28-94 OUT 10-18-94

Reviewed by Michael Nieves Date 10-18-94

EPA Reg. No. or File Symbol 62432-1

EPA Petition or EUP No. None

Date Division Received 9-6-94

Type Product Animal and Agriculture Broad Disinfectant

MRID No(s) None

Product Manager R. Douglas (PM 32)

Product Name Virkon S

Company Name Antec International

Submission Purpose The submission is an application to add
additional microorganisms: Aspergillus
fumigatus and Porcine Reproductive and
Respiratory Syndrome (PRRS) virus.

Type Formulation Liquid

Active Ingredients(s)

Potassium peroxymonosulfate..... 20.4%
Sodium chloride..... 1.5%

EFFICACY EVALUATION AND TECHNICAL MANAGEMENT SECTION

EFFICACY REVIEW -II

ANTIMICROBIAL PROGRAM BRANCH

EPA Reg. No. or File Symbol 62432-1
EPA Petition or EUP No. None
Date Division Received 9-6-94
Type Product Animal and Agriculture Broad Disinfectant
MRID No(s) None
Product Manager R. Douglas (PM 32)
Product Name Virkon S
Company Name Antec International

200.0 Introduction:

200.1 Uses:

See attached proposed label dated 9-6-94.

200.2 Background Information:

The submission is an application to add additional microorganisms: *Aspergillus fumigatus* and Porcine Reproductive and Respiratory Syndrome (PRRS) virus.

200.3 Factors Affecting Amount/Type of Data Required:

None

201.0 Data Summary

None

201.1 Abstract of Test Reports:

None

201.2 Brief Description of Tests:

No efficacy data was submitted with this submission.

201.3 Data Summaries

None

201.4 Other Summarized Results:

See Recommendations under 202.0.

202.0 Recommendations

202.1 Efficacy Supported By The Data:

No efficacy data was submitted with this submission because the labeling amendments are not related to human health.

203.0 Labeling:

The labeling amendments to add additional microorganisms: Aspergillus fumigatus and Porcine Reproductive and respiratory Syndrome (PRRS) virus are acceptable.

A.

DR. ALAN R. WAGNER
Regulatory Affairs and Technical Services

N

Private Consultation

4302 S.W. 147th Place
Miami, Florida 33185

(305) 553-9017

August 29, 1994

Ms. Ruth G. Douglas (PM32)
Antimicrobial Program Branch
Registration Division (7505C)
U.S. Environmental Protection Agency
401 M Street S.W.
Washington, D.C. 20460

Subject: Virkon S (EPA Reg. # 62432)

Dear Ms. Douglas

In accordance with our recent telephone conversation, please find for your review "Application For Pesticide Amendment" updating our EPA Master Label application that was submitted on June 24, 1994. We have received a notice from your agency dated July 11, 1994 informing us of receipt of the application of amendment and that it has passed an administrative screen for completeness. It was also determined at this time that the application qualifies for fast track review and the package will be forwarded to you for review to determine its acceptability.

Also, as we discussed, Ms. Douglas, we hope that the attached updated amendment will be joined with the application amendment of June 24, 1994 so as not to delay the review process.

We have highlighted the additions on the updated Master Label as you requested and have submitted 5 draft labels reflecting the modifications.

Thank you for your encouragement and assistance in expediting the joining of the two amendments and the courtesy extended to me during my visits at your agency and our telephone conversations. I shall be looking forward to our next meeting in Washington.

Sincerely

Alan R. Wagner

Alan R. Wagner, D.V.M., M.S.
Manager, Regulatory Affairs
Agent for Antec International Ltd.

ARW/mw

Attachments





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

09/08/94

ALAN WAGNER
DR ALAN WAGNER, DVM, MS
4302 SW 147 PLACE
MIAMI FL 33185

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

PRODUCT NAME: VIRKON S
COMPANY NAME: DR ALAN WAGNER, DVM, MS
OPP IDENTIFICATION NUMBER: 191018
EPA REGISTRATION NUMBER: 62432-1
EPA RECEIPT DATE: 09/06/94

SUBJECT: RECEIPT OF AMENDMENT

DEAR REGISTRANT:

The Office of Pesticide Programs has received your application for an amendment and it has passed an administrative screen for completeness.

During the initial screen we determined that the application qualifies for fast track review. The package will now be forwarded to the Product Manager for review to determine its acceptability.

If you have any questions, please contact Ruth Douglas, Product Manager 32, at (703)-305-7964.

Sincerely,

J. Wrice

Front End Processing Staff
Information Services Branch
Program Management and Support Division



Recycled/Recyclable
Printed with Soy/Canola ink on paper that
contains at least 50% recycled fiber

AMENDMENT

App # 191018

FAST TRACK * APPLICATION FOR AMENDMENT

WITH DATA

Init. Date

FEU

SIG (DATA)

FEU

PM

NO DATA

Init. Date

FEU

32
PM

2-11-9-2-94

REGULAR APPLICATION FOR AMENDMENT

WITH DATA

Init. Date

FEU

SIG (DATA)

PM


NO DATA

Init. Date

FEU

PM

- * Front End Processing determined this application qualifies for fast track review based on registrants claim of "me-too". No screen for substantial similarity is made by the Front End.

(A) 	United States Environmental Protection Agency Office of Pesticide Programs (H7505C) Washington, DC 20460	<input type="checkbox"/> Registration	OPP Identifier Number 191018
		<input checked="" type="checkbox"/> Amendment	
Application for Pesticide:		<input type="checkbox"/> Other	

Section I

1. Company/Product Number 62432 - (2. EPA Product Manager Ms. Ruth G. Douglas	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Virkon S	PM# 32	
5. Name and Address of Applicant (Include ZIP Code) Antec International Ltd Chilton Industrial Estate Sudbury, Suffolk CO10 6XD ENGLAND	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name: _____	
<input type="checkbox"/> Check if this is a new address		

Section II

<input checked="" type="checkbox"/> Amendment - Explain below	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Submission of Amendment for updating Master EPA Submission of June 24, 1994, and passed an administrative screen for completeness and qualified for Fast Track review on July 11, 1994

Section III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input type="checkbox"/> Metal	<input checked="" type="checkbox"/> Plastic
				<input type="checkbox"/> Glass	<input type="checkbox"/> Paper
				<input type="checkbox"/> Other (Specify) _____	
* Certification must be submitted.					
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) of Retail Container 2.5 Kg., 5.0 Kg., 25 Kg., 35 grams, 50 grams		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner In Which Label Is Affixed To Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input checked="" type="checkbox"/> Other (Pressure Sensitive)			

Section IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Alan R. Wagner, D.V.M., M.S.	Title Manager, Regulatory Affairs Agent for Antec International Ltd.	Telephone No. (Include Area Code) 305/553-9017
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature Alan R. Wagner D.V.M., M.S.	3. Title Manager, Regulatory Affairs Agent for Antec International Ltd.	
4. Typed Name Alan R. Wagner, D.V.M., M.S.	5. Date August 29, 1994	

PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

PAPERWORK REDUCTION ACT NOTICE: Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503.

INSTRUCTIONS: This form is to be used for all applications for new registration, and use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

1. Certification with Respect to Citation of Data (EPA Form 8570-29). [If not exempted by 40 CFR 152.81 (b) (4)];
2. Confidential Statement of Formula (EPA Form 8570-4);
3. Formulator's Exemption Statement (EPA Form 8570-27);
4. Five copies of draft labeling;
5. Three copies of any data submitted;
6. Authorization letter where applicable;
7. Matrices where applicable.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper or a mockup of the proposed label. If prepared as a mockup, it should be constructed in such a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission.

Submission of Data - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

SPECIFIC INSTRUCTIONS: Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended registration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.

Block A - Check the appropriate action for which you are submitting this form.

SECTION I - This section must be completed, as applicable, for all registration actions.

1. **Company/Product Number** - Insert your Company Number, if one has been assigned by EPA. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
2. **EPA Product Manager** - If known, fill in the name and PM number of the EPA Product Manager.
3. **Proposed Classification** - Specify the proposed classification of this product.
4. **Product Name** - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
5. **Name and Address of Applicant** - The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
6. **Expedited Review** - FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

SECTION II - This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA-registered product. This section is not to be used for a new application for registration.

1. **Subject of submission** - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; general label revision of use directions." Attach a separate page if additional space is needed.

SECTION III (Packaging and Container Information) - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

1. **Type of Packaging** - Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
2. **Type of Retail Container** - Indicate type of container in which product will be marketed.
3. **Location of Net Contents** - Specify the net contents of all retail containers for your product.
4. **Size(s) of Retail Container** - Specify the net contents of all retail containers for your product.
5. **Location of Use Directions** - Indicate the location of the use directions for your product.
6. **Manner in which label is affixed to product** - Indicate the method product label is attached to retail container.

SECTION IV (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me-too," reregistration, etc.

- 1-5. Self-explanatory.
6. EPA Use Only.

Reviewer ID

Submission No.

Data Package No.

W Powell

5432810

CODING FORM FOR APPLICATIONS FOR REGISTRATION/AMENDMENTS

File Symbol/Reg. No. 62432-1 PM 32 Action Code 300

10 Descriptor (Amend/Resubmissions only) general revisions

5 Intrastate Call-in ☐ (Y) Yes ☐ (N) No 15 Child-resistant Packaging ☐ (C) Certification ☐ (S) Service Person

20 Registration Type: ☐ (1) Conditional ☐ (2) Unconditional ☐ (R) Non-residential Use Only ☒ (N) Not-Applicable

25 Proposed Classification: 30 Final Classification: ☐ (R) Restricted ☐ (G) General ☐ (R) Restricted ☐ (N) Not Classified

35 Date on Application: 12 03 92 04 EPA Received Date: 12 08 92 40 Date Received by PM: 12 10 92
MO DAY YR MO DAY YR MO DAY YR

80 Method of Support: ☐ (1) Cite-All ☐ (6) Owner Submission ☒ (4) Not Applicable ☐ (7) Total Submission ☐ (5) Not Submitted ☐ (8) Selective Method

Reviewers Requested:	DATE SENT	DUE DATE	DATE RETURNED	RESPONSE CODE	RESPONSE DATE
CH					
EF					
PL					
DEB					
NDEB					
TB					
EEB					
EFGB					

115 FINAL ACTION Response Code 17

120 Response 09 29 93

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

29 SEP 1993

Richard J. Otten, Agent for
Antec International Ltd.
Windham Road
Chilton Industrial Estate, Sudbury
Suffolk, CO106XD England

Subject: Virkon S
EPA Registration No. 62432-1
Your Labeling Dated December 3, 1992

Dear Mr. Otten:

The amended labeling referred to above, with minor revisions and new company name, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable subject to the comments listed below. A stamped copy is enclosed for your records.

1. Place the Storage and Disposal section in the Directions for Use section.

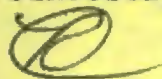
2. Submit five copies of the finished labeling before the product is released for shipment bearing the amended labeling.

Submit a letter for our records, on the registrant's company letterhead or notarized, authorizing you to act as their agent in registration matters with EPA.

Note that we do not review alternate distributor labels for acceptance.

If you have any questions about these comments, you may call Wallace Powell at 703-305-6938.

Sincerely,



Ruth G. Douglas
Product Manager 32
Antimicrobial Program Branch
Registration Division (H-7504C)

Enclosure

CONCURRENCES								
SYMBOL								
SURNAME								
DATE								

**Antec
International**

**V
(Virkon logo)**

**VIRKON® S
BROAD SPECTRUM DISINFECTANT**

**For Use in Cleaning and Disinfecting Industrial
Animal and Agricultural Facilities**

EFFECTIVE AGAINST:

BACTERIA

Streptococcus pyogenes
Campylobacter pyloridis
Klebsiella pneumoniae
Escherichia coli
Salmonella typhimurium
Salmonella choleraesuis
Pseudomonas aeruginosa
Staphylococcus aureus
Staphylococcus epidermidis
Mycoplasma gallisepticum

VIRUSES OF

Newcastle Disease
Infectious Bronchitis
Infectious Bursal Disease

Avian Laryngotracheitis
Avian Influenza

FUNGI

Aspergillus flavus
Candida albicans

ACTIVE INGREDIENTS

Potassium peroxymonosulfate..... 20.4%

Sodium Chloride..... 1.5%

INERT INGREDIENTS..... 78.1%

TOTAL.....100.0%

Equivalent to 9.75% Available Chlorine

**KEEP OUT OF REACH OF CHILDREN
DANGER:**

See Back Panel for Additional Precautions

11 lbs (5Kg) Net Weight

Distributed By:

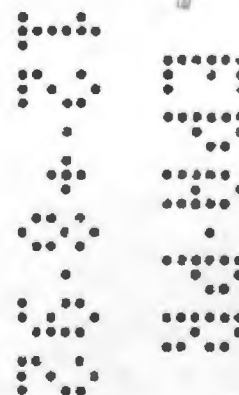
MICROTEC Animal Nutrition, Inc.

301 Baybrook Street, Thomasville, GA 31792, phone 912-225-1182

VIRKON S is a registered trademark of and manufactured by Antec International Limited

U.S. Patent No. 4822512

ACCEPTED
WITH COMMENTS
in EPA Letter Dated
29 SEP 1993
Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide
registered under EPA Reg. No.
62432-1



BROAD SPECTRUM DISINFECTANT

VIRKON S is effective against numerous microorganisms affecting animals: viruses, gram positive and gram negative bacteria, fungi (molds and yeasts), and mycoplasma. Efficacy was determined in the presence of hard water and organic material.

CONTROLS

Viruses of Newcastle Disease, Infectious Bronchitis, Infectious Bursal Disease, Laryngotracheitis, and Avian Influenza.

Fungi (molds and yeasts) - *Aspergillus flavus* and *Candida albicans*.

Bacteria - *Streptococcus pyogenes*, *Campylobacter pyloridis*, *Kiebsiella pneumoniae*, *Escherichia coli*, *Salmonella typhimurium*, *Salmonella choleraesuis*, *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Staphylococcus epidermidis*, *Mycoplasma gallisepticum*.

DIRECTIONS FOR USE

Federal law prohibits use of this product in a manner inconsistent with its labeling.

This powder formula is easily diluted for use in manual or machine operations.

VIRKON S is recommended for use in hatcheries, chicken houses, and processing plants.

HATCHERIES: **VIRKON S** at 1% solution is generally suitable for cleaning and disinfecting hatchers, setters, evaporative coolers, humidifying systems, ceiling fans, chicken houses, transfer trucks, trays, and plastic chick boxes (use 2% solution for *Mycoplasma* and *Aspergillus flavus*).

VIRKON S is recommended for use in fogging (wet misting) operations as an adjunct either preceding or following regular cleaning and disinfecting procedures. **VIRKON S** at 1-2% solution is suitable. Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions.

BROILER/BREEDER HOUSES: Following removal of chickens, feed, and water troughs, remove manure and litter and spray floors and side walls with **VIRKON S** at 1% solution. Thoroughly wash waterers and feeders with a 1% solution of **VIRKON S** (use 2% solution for *Mycoplasma* and *Aspergillus flavus*). After contact for 10 minutes, rinse with potable water. Do not use to house poultry or employ equipment until treatment has dried.

FOR AIR SANITIZING: Use **VIRKON S** at 1-2% solution. Fog the atmosphere until surfaces are moist. Allow at least 2 hours before entering area that has been fogged.

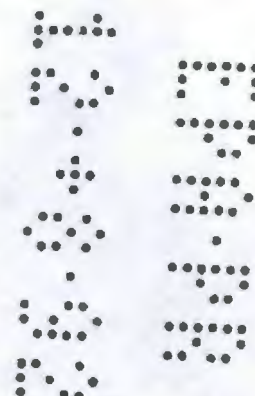
PROCESSING PLANTS: For disinfecting and cleaning walls, ceilings, and floors spray at a dilution of 1%.

ACCEPTED
with COMMENTS
in EPA Letter Dated:

29 SEP 1993

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide
registered under EPA Reg. No.

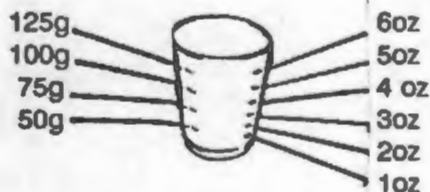
62432-1



VIRKON® S

DILUTION CHART

Quantity of Final Solution	1% Solution	2% Solution
American		
1 gallon	1.3 ounces	2.7 ounces
10 gallons	13.4 ounces	26.7 ounces
50 gallons	66.8 ounces	133.5 ounces
Metric		
10 liters	100 grams	200 grams
50 liters	500 grams	1000 grams
200 liters	2 kgs	4 kgs



Brim full - contains
200g or 7 ounces



The measure cap holds when
filled level 500g or 17.5 ounces.

ACCEPTED
with COMMENTS
in EPA Letter D-100
29 SEP 1993
Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide
registered under EPA Reg. No.
62432-1

For DISINFECTING use a rate of 7.5 gallons/1000 sq. ft.

For CLEANING AND DISINFECTING use a rate of 15 gallons/1000 sq. ft.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER

Corrosive. Causes skin burns and irreversible eye damage. Harmful if swallowed, absorbed through skin, or inhaled. Do not get in eyes, on skin, or on clothing. Wear protective clothing and rubber gloves. Avoid breathing dust. Wear goggles, face shield, or safety glasses. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

PRACTICAL TREATMENT

IF IN EYES: Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes. Get prompt medical attention.

IF ON SKIN: Wash with plenty of soap and water. Get medical attention if irritation persists.

IF INHALED or symptoms of coughing, choking, or wheezing are troublesome, remove to fresh air and seek medical attention.

IF SWALLOWED: Drink promptly a large quantity of water. Avoid alcohol. Get immediate medical attention.

NOTICE OF PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

STORAGE AND DISPOSAL - Store in a cool, dry place in tightly closed container. Always replace lid after use. Wash empty container thoroughly and dispose of in trash.

Manufactured for

MICROTEC Animal Nutrition, Inc.

301 Baybrook Street, Thomasville, GA 31792, phone 912-225-1182

EPA Reg. No. 62432-1

EPA Est. No. 62432-EN-001

DATE: 12-10-82

TO: FILE ROOM _____
DOCUMENT CENTER _____
PRODUCT MANAGER 32 _____
PAM (ROOM 263) _____
FROM: FRANCES WRICE *FW* _____

TYPE OF REGISTRATION

FAST - TRACK ACTION (with data/without data)

This action has been determined to be a fast-track action by FEPS and must be entered in the PRATS using one of the following codes:

- 160 - Application for "me-to" registration
- 170 - Application for registration - old chemical - "Me-too" with additional use.
- 300 - Amendment - label revision - administrative (no data required).
- 305 - Amendment - label revision - data required does not need HED/EFED review.
- 310 - Amendment - added "me-too" Use - no HED/EFED review needed.
- 345 - Formula change - no HED/EFED review required.

REGULAR REGISTRATION (with data/without data)

24C NEW

24C AMENDMENT

RESUBMISSION (response to Agency ltr)

FINAL PRINTED LABELS

OTHER

MESSAGE: _____



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

12/10/92

S.R. CRAGG -PHONE:0787 77305
ANTEC INTERNATIONAL LTD
WINDHAM ROAD, CHILTON INDUSTRIAL ESTATE
SUDBURY, SUFFOLK 00000

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

Product Name: VIRKON S
Company Name: ANTEC INTERNATIONAL LTD.
Application No.: 156034
EPA Reg. No.: 62432-1
EPA Receipt Date: 12/08/92

Subject: Front End Screen for an Amendment

Dear Sir or Madam:

Your application for registration has been received by the Office of Pesticide Programs and has passed a preliminary screen for completeness. It will be placed in line for review to determine its acceptability. The application will be processed in chronological order of receipt.

Although the 1988 FIFRA amendments mandate EPA to review applications for expedited registration or amendments within 90 days, this turnaround time will not be met immediately due to the backlog of applications received before December 24, 1988. However, EPA is increasing human and automated resources and making necessary procedural changes in order to eliminate the backlog and to meet the 90-day response time as soon as possible.

If you have any questions, you may contact Ruth Douglas, Product Manager 32, at (703)-305-7964.

Sincerely,

Frances White

for

Team Leader
Front End Processing Staff
Registration Support Branch
Registration Division (H7504C)



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

12/10/92

S.R. CRAGG -PHONE:0787 77305
ANTEC INTERNATIONAL LTD
WINDHAM ROAD, CHILTON INDUSTRIAL ESTATE
SUDBURY, SUFFOLK 00000

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

Product Name: VIRKON S
Company Name: ANTEC INTERNATIONAL, LTD.
Application No.: 156033
EPA Reg. No.: 62432-1
EPA Receipt Date: 12/08/92

Subject: Front End Screen for an Amendment

Dear Sir or Madam:

Your application for registration has been received by the Office of Pesticide Programs and has passed a preliminary screen for completeness. It will be placed in line for review to determine its acceptability. The application will be processed in chronological order of receipt.

Although the 1988 FIFRA amendments mandate EPA to review applications for expedited registration or amendments within 90 days, this turnaround time will not be met immediately due to the backlog of applications received before December 24, 1988. However, EPA is increasing human and automated resources and making necessary procedural changes in order to eliminate the backlog and to meet the 90-day response time as soon as possible.

If you have any questions, you may contact Ruth Douglas, Product Manager 32, at (703)-305-7964.

Sincerely,

Frances White

for
Team Leader
Front End Processing Staff
Registration Support Branch
Registration Division (H7504C)

RICHARD J. OTTEN
Registration and Regulatory Services

December 3, 1992

Ms. Ruth Douglas
Product Manager, Team 32
Fungicide-Herbicide Branch
Registration Division (H-7505C)
Office of Pesticides and Toxic Substances
U.S. Environmental Protection Agency
Washington, DC 20460

RE: EPA Registration No. 62432-1
VIRKON-S

Dear Ms. Douglas:

Attached please find five copies of two revised texts for the product cited above.

This product was originally registered by A.H. Robins; EPA Reg. No. 778-91. Several months ago the registration was transferred to the manufacturer, Antec International, Ltd., by EPA and assigned the new number shown above.

Other changes included are:

1. Showing Microtec Animal Nutrition as the primary distributor for Antec in the U.S. under the Antec EPA Registration number, not under a supplemental distributor number.
2. Showing the company DURVET as a secondary distributor, again using Antec's EPA Registration number only.
3. Minor editorial changes such as inserting the word "solution" in several places following percentage figures and deleting two microbial species which were listed on the A.H. Robins label.

We will appreciate your review and response as promptly as possible. As you well know, it takes many months to finalize

5116 Wood Valley Drive, Raleigh, NC 27613 Office (919) 846-7860 Telefax (919) 846-2775

Ms. Ruth Douglas
December 3, 1992
Page 2

printed labels, package product, etc., and we need to know as soon as possible that no additional changes will be required by EPA.

Sincerely,



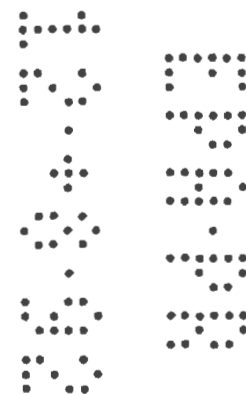
Richard J. Otten
U.S. Agent of Record
Antec International, Ltd.

RJO/dgm

Enclosures:

1. EPA Form 8570-1 with Antec Label
2. EPA Form 8570-1 with Durvet Label

cc: Antec International, Ltd. (R. Auchincloss)
Microtec (G. Myers)
Phoenix Regulatory Associates (C.K. Gund)



Durvet

V
(Virkon logo)

VIRKON® S
BROAD SPECTRUM DISINFECTANT

For Use in Cleaning and Disinfecting Industrial
Animal and Agricultural Facilities

EFFECTIVE AGAINST:

BACTERIA

Streptococcus pyogenes
Campylobacter pyloridis
Klebsiella pneumoniae
Escherichia coli
Salmonella typhimurium
Salmonella choleraesuis
Pseudomonas aeruginosa
Staphylococcus aureus
Staphylococcus epidermidis
Mycoplasma gallisepticum

VIRUSES OF

Newcastle Disease
Infectious Bronchitis
Infectious Bursal Disease

Avian Laryngotracheitis
Avian Influenza

FUNGI

Aspergillus flavus
Candida albicans

ACTIVE INGREDIENTS

Potassium peroxymonosulfate..... 20.4%
Sodium Chloride..... 1.5%
INERT INGREDIENTS..... 78.1%
TOTAL.....100.0%

Equivalent to 9.75% Available Chlorine

KEEP OUT OF REACH OF CHILDREN

DANGER:

See Back Panel for Additional Precautions

11 lbs (5Kg) Net Weight

Agents for Antec:

MICROTEC Animal Nutrition, Inc.

301 Baybrook Street, Thomasville, GA 31792, phone 912-225-1182

VIRKON S is a registered trademark of and manufactured by Antec International Limited

U.S. Patent No. 4,822,312

BROAD SPECTRUM DISINFECTANT

VIRKON S is effective against numerous microorganisms affecting animals: viruses, gram positive and gram negative bacteria, fungi (molds and yeasts), and mycoplasma. Efficacy was determined in the presence of hard water and organic material.

CONTROLS

Viruses of Newcastle Disease, Infectious Bronchitis, Infectious Bursal Disease, Laryngotracheitis and Avian Influenza.

Fungi (molds and yeasts) - *Aspergillus flavus* and *Candida albicans*.

Bacteria - *Streptococcus pyogenes*, *Campylobacter pyloridis*, *Klebsiella pneumoniae*, *Escherichia coli*, *Salmonella typhimurium*, *Salmonella choleraesuis*, *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Staphylococcus epidermidis*, *Mycoplasma gallisepticum*.

DIRECTIONS FOR USE

Federal law prohibits use of this product in a manner inconsistent with its labeling.

This powder formula is easily diluted for use in manual or machine operations.

VIRKON S is recommended for use in hatcheries, chicken houses, and processing plants.

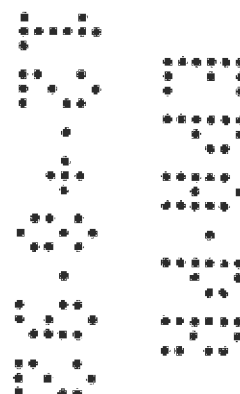
HATCHERIES: **VIRKON S** at 1% solution is generally suitable for cleaning and disinfecting hatchers, setters, evaporative coolers, humidifying systems, ceiling fans, chicken houses, transfer trucks, trays, and plastic chick boxes (use 2% solution for *Mycoplasma* and *Aspergillus flavus*).

VIRKON S is recommended for use in fogging (wet misting) operations as an adjunct either preceding or following regular cleaning and disinfecting procedures. **VIRKON S** at 1-2% solution is suitable. Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions.

BROILER/BREEDER HOUSES: Following removal of chickens, feed, and water troughs, remove manure and litter and spray floors and side walls with **VIRKON S** at 1%. Thoroughly wash waterers and feeders with a 1% solution of **VIRKON S** (use 2% solution for *Mycoplasma* and *Aspergillus flavus*). After contact for 10 minutes, rinse with potable water. Do not use to house poultry or employ equipment until treatment has dried.

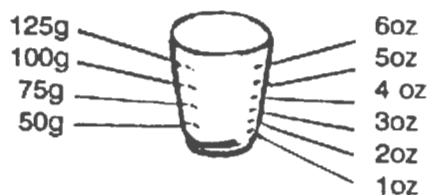
FOR AIR SANITIZING: Use **VIRKON S** at 1-2% solution. Fog the atmosphere until surfaces are moist. Allow at least 2 hours before entering area that has been fogged.

PROCESSING PLANTS: For disinfecting and cleaning walls, ceilings, and floors spray at a dilution of 1%.



VIRKON® S**DILUTION CHART**

Quantity of Final Solution	1% Solution	2% Solution
American		
1 gallon	1.3 ounces	2.7 ounces
10 gallons	13.4 ounces	26.7 ounces
50 gallons	66.8 ounces	133.5 ounces
Metric		
10 liters	100 grams	200 grams
50 liters	500 grams	1000 grams
200 liters	2 kgs	4 kgs



Brim full - contains
200g or 7 ounces



The measure cap holds when
filled level 500g or 17.5 ounces.

For **DISINFECTING** use a rate of 7.5 gallons/1000 sq. ft.

For **CLEANING AND DISINFECTING** use a rate of 15 gallons/1000 sq. ft.

PRECAUTIONARY STATEMENTS**HAZARDS TO HUMANS AND DOMESTIC ANIMALS****DANGER**

Corrosive. Causes skin burns and irreversible eye damage. Harmful if swallowed, absorbed through skin, or inhaled. Do not get in eyes, on skin, or on clothing. Wear protective clothing and rubber gloves. Avoid breathing dust. Wear goggles, face shield, or safety glasses. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

PRACTICAL TREATMENT

IF IN EYES: Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes. Get prompt medical attention.

IF ON SKIN: Wash with plenty of soap and water. Get medical attention if irritation persists.

IF INHALED or symptoms of coughing, choking, or wheezing are troublesome, remove to fresh air and seek medical attention.

IF SWALLOWED: Drink promptly a large quantity of water. Avoid alcohol. Get immediate medical attention.

NOTICE OF PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

STORAGE AND DISPOSAL - Store in a cool, dry place in tightly closed container. Always replace lid after use. Wash empty container thoroughly and dispose of in trash.

Manufactured for:
DURVET, Inc.
Blue Springs, Missouri 64015

RICHARD J. OTTEN
Registration and Regulatory Services

December 3, 1992

Ms. Ruth Douglas
Product Manager, Team 32
Fungicide-Herbicide Branch
Registration Division (H-7505C)
Office of Pesticides and Toxic Substances
U.S. Environmental Protection Agency
Washington, DC 20460

RE: EPA Registration No. 62432-1
VIRKON-S

Dear Ms. Douglas:

Attached please find five copies of two revised texts for the product cited above.

This product was originally registered by A.H. Robins; EPA Reg. No. 778-91. Several months ago the registration was transferred to the manufacturer, Antec International, Ltd., by EPA and assigned the new number shown above.

Other changes included are:

1. Showing Microtec Animal Nutrition as the primary distributor for Antec in the U.S. under the Antec EPA Registration number, not under a supplemental distributor number.
2. Showing the company DURVET as a secondary distributor, again using Antec's EPA Registration number only.
3. Minor editorial changes such as inserting the word "solution" in several places following percentage figures and deleting two microbial species which were listed on the A.H. Robins label.

We will appreciate your review and response as promptly as possible. As you well know, it takes many months to finalize

Ms. Ruth Douglas
December 3, 1992
Page 2

printed labels, package product, etc., and we need to know as soon as possible that no additional changes will be required by EPA.

Sincerely,



Richard J. Otten
U.S. Agent of Record
Antec International, Ltd.

RJO/dgm

Enclosures:

1. EPA Form 8570-1 with Antec Label
2. EPA Form 8570-1 with Durvet Label

cc: Antec International, Ltd. (R. Auchincloss)
Microtec (G. Myers)
Phoenix Regulatory Associates (C.K. Gund)

<div style="display: flex; align-items: center; justify-content: center;"><div style="margin-right: 10px;">(A)</div></div> <div style="text-align: center;"><p>United States Environmental Protection Agency Office of Pesticide Programs (H7505C) Washington, DC 20460</p><p>Application for Pesticide:</p></div>		<div style="display: flex; flex-direction: column; align-items: center;"><div style="border: 1px solid black; width: 20px; height: 20px; margin-bottom: 5px;"></div><div style="border: 1px solid black; width: 20px; height: 20px; margin-bottom: 5px; text-align: center;">X</div><div style="border: 1px solid black; width: 20px; height: 20px;"></div></div>	<p>Registration</p> <p>Amendment</p> <p>Other</p>	<p>OPP Identifier Number</p> <p style="font-size: 1.2em; color: red;">156034</p>							
		<p>Section I</p>									
<p>1. Company/Product Number</p> <p>EPA Reg. No. 62432-1</p>		<p>2. EPA Product Manager</p> <p>Ruth Douglass</p>		<p>3. Proposed Classification</p> <div style="display: flex; justify-content: space-around;"><div><input checked="" type="checkbox"/> None</div><div><input type="checkbox"/> Restricted</div></div>							
<p>4. Company/Product (Name)</p> <p>Antec International Limited VIRKON S</p>		<p>PM#</p> <p>32</p>		<p>6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:</p> <p>EPA Reg. No. _____</p> <p>Product Name _____</p>							
<p>5. Name and Address of Applicant (Include ZIP Code)</p> <p>Antec International, Ltd. Chilton Industrial Estate, Sudbury Suffolk CO106XD England</p> <div style="margin-top: 10px;"><input type="checkbox"/> Check if this is a new address</div>											
<p>Section II</p>											
<div style="display: flex; flex-direction: column;"><div><input checked="" type="checkbox"/> Amendment - Explain below</div><div><input type="checkbox"/> Resubmission in response to Agency letter dated _____</div><div><input type="checkbox"/> Notification - Explain below.</div></div>			<div style="display: flex; flex-direction: column;"><div><input type="checkbox"/> Final printed labels in response to Agency letter dated _____</div><div><input type="checkbox"/> "Me Too" Application.</div><div><input type="checkbox"/> Other - explain below.</div></div>								
<p>Explanation: Use additional page(s) if necessary. (For section I and Section II.)</p> <div style="margin-left: 20px;"><p>1. Shows Antec as Registrant following transfer of registration from A.H. Robins.</p><p>2. Shows Microtec as agent/distributor for Antec's registration in U.S.</p><p>3. Inserts "solution" at several places in text following percentage figure.</p></div>											
<p>Section III</p>											
<p>1. Material This Product Will Be Packaged In:</p> <table border="1" style="width:100%; border-collapse: collapse;"><tr><td style="width: 25%; vertical-align: top;"><p>Child-Resistant Packaging</p><div style="display: flex; justify-content: space-between;"><div><input type="checkbox"/> Yes*</div><div><input checked="" type="checkbox"/> No</div></div></td><td style="width: 25%; vertical-align: top;"><p>Unit Packaging</p><div style="display: flex; justify-content: space-between;"><div><input type="checkbox"/> Yes</div><div><input checked="" type="checkbox"/> No</div></div><p>If "Yes," Unit Package wgt. No. per container</p></td><td style="width: 25%; vertical-align: top;"><p>Water Soluble Packaging</p><div style="display: flex; justify-content: space-between;"><div><input type="checkbox"/> Yes</div><div><input checked="" type="checkbox"/> No</div></div><p>If "Yes," Package wgt. No. per container</p></td><td style="width: 25%; vertical-align: top;"><p>2. Type of Container</p><div style="display: flex; justify-content: space-between;"><div><input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____</div><div>Coated Cardboard</div></div></td></tr></table> <p>* Certification must be submitted.</p>						<p>Child-Resistant Packaging</p> <div style="display: flex; justify-content: space-between;"><div><input type="checkbox"/> Yes*</div><div><input checked="" type="checkbox"/> No</div></div>	<p>Unit Packaging</p> <div style="display: flex; justify-content: space-between;"><div><input type="checkbox"/> Yes</div><div><input checked="" type="checkbox"/> No</div></div> <p>If "Yes," Unit Package wgt. No. per container</p>	<p>Water Soluble Packaging</p> <div style="display: flex; justify-content: space-between;"><div><input type="checkbox"/> Yes</div><div><input checked="" type="checkbox"/> No</div></div> <p>If "Yes," Package wgt. No. per container</p>	<p>2. Type of Container</p> <div style="display: flex; justify-content: space-between;"><div><input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____</div><div>Coated Cardboard</div></div>		
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<p>3. Location of Net Contents Information</p> <div style="display: flex; justify-content: space-around;"><div><input checked="" type="checkbox"/> Label</div><div><input type="checkbox"/> Container</div></div>		<p>4. Size(s) of Retail Container</p> <p>2.5Kg, 5.0 Kg, 25Kg, 50 grams, 35 grams</p>		<p>5. Location of Label Directions</p> <div style="display: flex; justify-content: space-around;"><div><input checked="" type="checkbox"/> On Label</div><div><input type="checkbox"/> On Labeling accompanying product</div></div>							
<p>6. Manner In Which Label Is Affixed To Product</p> <div style="display: flex; justify-content: space-between;"><div><input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled</div><div><input type="checkbox"/> Other (_____)</div></div>											
<p>Section IV</p>											
<p>1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)</p> <table border="1" style="width:100%; border-collapse: collapse;"><tr><td style="width: 40%;">Name</td><td style="width: 30%;">Title</td><td style="width: 30%;">Telephone No. (Include Area Code)</td></tr><tr><td>Richard J. Otten</td><td>U.S. Agent of Record</td><td>919-846-7860</td></tr></table>						Name	Title	Telephone No. (Include Area Code)	Richard J. Otten	U.S. Agent of Record	919-846-7860
Name	Title	Telephone No. (Include Area Code)									
Richard J. Otten	U.S. Agent of Record	919-846-7860									
<p style="text-align: center;">Certification</p> <p>I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.</p>					<p>6. Date Application Received (Stamped)</p>						
<p>2. Signature</p> <div style="text-align: center;"></div>		<p>3. Title</p> <p>U.S. Agent of Record</p>									
<p>4. Typed Name</p> <p>Richard J. Otten</p>		<p>5. Date</p> <p style="font-size: 1.2em;">12-3-92</p>									

PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

PAPERWORK REDUCTION ACT NOTICE: Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503.

INSTRUCTIONS: This form is to be used for all applications for new registration, end use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

1. Certification with Respect to Citation of Data (EPA Form 8570-29). [If not exempted by 40 CFR 152.81 (b) (4)];
2. Confidential Statement of Formula (EPA Form 8570-4);
3. Formulator's Exemption Statement (EPA Form 8570-27);
4. Five copies of draft labeling;
5. Three copies of any data submitted;
6. Authorization letter where applicable;
7. Matrices where applicable.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper or a mockup of the proposed label. If prepared as a mockup, it should be constructed in such a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission.

Submission of Data - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

SPECIFIC INSTRUCTIONS: Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended registration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.

Block A - Check the appropriate action for which you are submitting this form.

SECTION I - This section must be completed, as applicable, for all registration actions.

1. **Company/Product Number** - Insert your Company Number, if one has been assigned by EPA. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
2. **EPA Product Manager** - If known, fill in the name and PM number of the EPA Product Manager.
3. **Proposed Classification** - Specify the proposed classification of this product.
4. **Product Name** - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
5. **Name and Address of Applicant** - The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
6. **Expedited Review** - FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

SECTION II - This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA-registered product. This section is not to be used for a new application for registration.

1. **Subject of Submission** - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; general label revision of use directions." Attach a separate page if additional space is needed.

SECTION III (Packaging and Container Information) - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

1. **Type of Packaging** - Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
2. **Type of Retail Container** - Indicate type of container in which product will be marketed.
3. **Location of Net Contents** - Specify the net contents of all retail containers for your product.
4. **Size(s) of Retail Container** - Specify the net contents of all retail containers for your product.
5. **Location of Use Directions** - Indicate the location of the use directions for your product.
6. **Manner in which label is affixed to product** - Indicate the method product label is attached to retail container.

SECTION IV (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me-too," reregistration, etc.

- 1-5. Self-explanatory.
6. EPA Use Only.

(A) EPA	United States Environmental Protection Agency Office of Pesticide Programs (H7505C) Washington, DC 20460 Application for Pesticide:	<input type="checkbox"/> Registration <input checked="" type="checkbox"/> Amendment <input type="checkbox"/> Other	OPP Identifier Number <div style="font-size: 1.5em; font-weight: bold; color: red;">156033</div>
------------------------------	---	---	---

Section I

1. Company/Product Number EPA Reg. No. 62432-1	2. EPA Product Manager Ruth Douglas	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Antec International Limited VIRKON S	PM# 32	
5. Name and Address of Applicant (Include ZIP Code) Antec International, Ltd. Chilton Industrial Estate, Sudbury Suffolk CO106XD England <input type="checkbox"/> Check if this is a new address		
6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____		

Section II

<input checked="" type="checkbox"/> Amendment - Explain below <input type="checkbox"/> Resubmission in response to Agency letter dated _____ <input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____ <input type="checkbox"/> "Me Too" Application. <input type="checkbox"/> Other - explain below.
---	---

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

1. Shows Antec as registrant following transfer of registration from A.H. Robins
2. Shows Microtec as Agent for Antec and Durvet as local distributor
3. Inserts "solution" at several places in text following percentage figures.

Section III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____	
* Certification must be submitted.		If "Yes," Unit Package wgt. No. per container	If "Yes," Package wgt. No. per container		
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) of Retail Container 2.5Kg, 5.0Kg, 25Kg 50 grams, 35 grams		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
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Section IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Richard J. Otten	Title U.S. Agent of Record	Telephone No. (Include Area Code) 919-846-7860

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature 	3. Title U.S. Agent of Record	<div style="font-size: 1.5em; font-weight: bold;">135</div>
4. Typed Name Richard J. Otten	5. Date 12-3-92	

PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

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2. **EPA Product Manager** - If known, fill in the name and PM number of the EPA Product Manager.
3. **Proposed Classification** - Specify the proposed classification of this product.
4. **Product Name** - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
5. **Name and Address of Applicant** - The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
6. **Expedited Review** - FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

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1. **Subject of submission** - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; general label revision of use directions." Attach a separate page if additional space is needed.

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SECTION IV (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me-too," reregistration, etc.

- 1-5. Self-explanatory.
6. EPA Use Only.

Reviewer ID

Submission No.

Data Package No.

Douglas3408840

CODING FORM FOR APPLICATIONS FOR REGISTRATION/AMENDMENTS

File Symbol/Reg. No.

778-91

PM

32

Action Code

350

[10] Descriptor (Amend/Resubmissions only)

resub. amend study per 86-5

[5] Intrastate Call-in

☐

(Y) Yes

[15]

Child-resistant
Packaging☐

(C) Certification

☒

(N) No

☐

(S) Service Person

[20] Registration Type:

☐

(1) Conditional

☒

(2) Unconditional

☐(R) Non-residential
Use Only☐

(N) Not-Applicable

[25] Proposed Classification:

[30] Final Classification:

☐

(R) Restricted

☐

(R) Restricted

☒

(G) General

☒

(N) Not Classified

[35] Date on Application:

[04] EPA Received Date:

[40] Date Received by PM

11/1/91
MO DAY YR11/13/91
MO DAY YR11/26/91
MO DAY YR

[80] Method of Support:

☐

(1) Cite-All

☐

(6) Owner Submission

☐

(4) Not Applicable

☐

(7) Total Submission

☐

(5) Not Submitted

☐

(8) Selective Method

Reviewers Requested:

DATE
SENTDUE
DATEDATE
RETURNEDRESPONSE
CODERESPONSE
DATE

CH

EF

PL

DEB

NDEB

TB

EEB

EFGB

[115] FINAL Response
ACTION Code37

[120] Response

11/10/91
MO DAY YR75-DAY RESPONSE DUE DATE: ☐ (Y) Yes☐ (N) No

PM 32

This is an accepted submission. One copy of the PPC diagnosis and one of the annotated bibliography are provided for your files. The PPC has already mailed out the submitter's copies of the two documents.

This is a partially accepted/rejected submission. A copy of the PPC diagnosis and of the annotated bibliography (if applicable) are provided for your files. A second copy is provided for your use in corresponding with the data submitter.

NOV 20 1991

U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs

A.H. ROBINS CO. INC.
P. O. BOX 26609
1405 CUMMINGS DR.
RICHMOND, VA 23261

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your transmittal of 11/15/91. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

420924-00

A. H. Robins Company
1407 Cummings Drive
P. O. Box 26609
Richmond, Virginia 23261-6609
FAX (804) 257-2670
Telephone (804) 257-2000

A-H-ROBINS
A Subsidiary of
American Home Products Corporation

Ms. Ruth G. Douglas
Acting Product Manager (32)
U.S. Environmental Protection
Agency
Antimicrobial Programs Branch
Registration Division (H-7504C)
Washington, DC 20460

November 6, 1991

Re: EPA Registration 778-91
Submission of Product
Chemistry for the Product
VirKon S (Disinfectant)

Dear Ms. Douglas:

VirKon S, EPA Registration No. 778-91, is approved by EPA as a broad spectrum disinfectant.

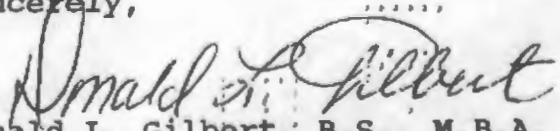
Enclosed, in triplicate, under Guideline No. 63-17, is a Product Chemistry Study. This study was originally submitted on May 31, 1991, and was rejected by EPA as not being in the proper format. It was resubmitted on October 15, 1991. 42092401

Today we received notification that the study was again rejected for not containing the proper flagging statement. We have added the flagging statement and hereby resubmit this study for your review.

The submitter, A. H. Robins Company, 1407 Cummings Drive, P. O. Box 26609, Richmond, VA 23261-6609, has conducted this study on VirKon S in addition to what was in the original submission. All work was done at 25 degrees Centigrade.

Please call me at (804) 257-2035 if there are any questions.

Sincerely,


Donald L. Gilbert, B.S., M.B.A.
Director, Regulatory Affairs
and Product Development
Special Products Division

Enclosures

Reviewer ID R Doug 126
Submission No. 5406180
Data Package No. _____

CODING FORM FOR APPLICATIONS FOR REGISTRATION/AMENDMENTS

File Symbol/Reg. No. 778-91 PM 32 Action Code 300
|10| Descriptor (Amend/Resubmissions only) prod. chemistry (63-17)
|5| Intrastate Call-in ☐ (Y) Yes |15| Child-resistant Packaging ☐ (C) Certification
☒ (N) No ☐ (S) Service Person
|20| Registration Type: ☐ (R) Non-residential Use Only
☐ (1) Conditional ☒ (2) Unconditional ☐ (N) Not-Applicable
|25| Proposed Classification: |30| Final Classification:
☐ (R) Restricted ☐ (R) Restricted
☐ (G) General ☐ (N) Not Classified
|35| Date on Application: |04| EPA Received Date: |40| Date Received by PM
10/15/91 10/22/91 10/28/91
MO DAY YR MO DAY YR MO DAY YR
|80| Method of Support:
☐ (1) Cite-All ☐ (6) Owner Submission
☒ (4) Not Applicable ☐ (7) Total Submission
☐ (5) Not Submitted ☐ (8) Selective Method

Reviewers Requested:	DATE SENT	DUE DATE	DATE RETURNED	RESPONSE CODE	RESPONSE DATE
CH					
EF					
PL					
DEB					
NDEB					
TB					
EEB					
EFGB					

|115| FINAL Response ACTION Code 10 |120| Response 11/9/91
MO DAY YR

75-DAY RESPONSE DUE DATE: ☐ (Y) Yes ☐ (N) No

U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs

01 NOV 1991

A.H. ROBINS CO. INC.
P. O. BOX 26609
1405 CUMMINGS DR.
RICHMOND, VA 23261

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your transmittal of 10/22/91. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

We are unable to accept your data submittal for further processing and review, because of the significant deficiencies noted below. It is being returned to you for correction. If deficiencies were found which apply to your overall submission, they are described immediately following this paragraph. If problems are found with individual studies, they are described below linked to the study identifier found on the enclosed copy of your bibliography.

Rejected study [01] :

You must include the appropriate flagging statement for this study as specified in 40 CFR 158.34. This statement must be signed and dated by an authorized representative of the company.

A. H. Robins Company
1407 Cummings Drive
P. O. Box 26609
Richmond, Virginia 23261-6609
FAX (804) 257-2670
Telephone (804) 257 2000

A-H-ROBINS
A Subsidiary of
American Home Products Corporation

Ms. Ruth G. Douglas
Acting Product Manager (32)
U.S. Environmental Protection
Agency
Antimicrobial Programs Branch
Registration Division (H-7504C)
Washington, DC 20460

October 15, 1991

Re: EPA Registration 778-91
Submission of Product
Chemistry for the Product
VirKon S (Disinfectant)

Dear Ms. Douglas:

VirKon S, EPA Registration No. 778-91, is approved by EPA as a broad spectrum disinfectant.

Reject (P1) [Enclosed, in triplicate, under Guideline No. 63-17, is a Product Chemistry Study. This study was originally submitted on May 31, 1991, and was rejected by EPA as not being in the proper format.

The submitter, A. H. Robins Company, 1407 Cummings Drive, P. O. Box 26609, Richmond, VA 23261-6609, has conducted this study on VirKon S in addition to what was in the original submission. All work was done at 25 degrees Centigrade.

Please call me at (804) 257-2035 if there are any questions.

Sincerely,

Donald L. Gilbert
Donald L. Gilbert, B.S., M.B.A.
Director, Regulatory Affairs
and Product Development
Special Products Division

Enclosures

PM 32

This is an accepted submission. One copy of the PPC diagnosis and one of the annotated bibliography are provided for your files. The PPC has already mailed out the submitter's copies of the two documents.

✓ This is a ~~rejected~~ submission. A copy of the PPC diagnosis and of the annotated bibliography (if applicable) are provided for your files. A second copy is provided for your use in corresponding with the data submitter.

Reviewer ID

WDDGE ✓

Submission No.

5397319

Data Package No.

CODING FORM FOR APPLICATIONS FOR REGISTRATION/AMENDMENTS

File Symbol/Reg. No.

778-91

PM

32

Action Code

345

[10] Descriptor (Amend/Resubmissions only)

stability data

[5]

Intrastate Call-in

☐

(Y) Yes

[15]

Child-resistant
Packaging☐

(C) Certification

☒

(N) No

☐

(S) Service Person

[20] Registration Type:

☐

(1) Conditional

☒

(2) Unconditional

☐(R) Non-residential
Use Only☐

(N) Not-Applicable

[25] Proposed Classification:

[30] Final Classification:

☐

(R) Restricted

☐

(R) Restricted

☒

(G) General

☒

(N) Not Classified

[35] Date on Application:

[04] EPA Received Date:

[40] Date Received by PM

05/31/91
MO DAY YR06/04/91
MO DAY YR06/07/91
MO DAY YR

[80] Method of Support:

☐

(1) Cite-All

☐

(6) Owner Submission

☒

(4) Not Applicable

☐

(7) Total Submission

☐

(5) Not Submitted

☐

(8) Selective Method

SEP 25 1991

Reviewers Requested:

DATE
SENTDUE
DATEDATE
RETURNEDRESPONSE
CODERESPONSE
DATE

✓ CH

EF

PL

DEB

NDEB

TB

EEB

EFGB

[115] FINAL Response
ACTION Code

38

[120] Response

09/25/91
MO DAY YR

W.E.W.

75-DAY RESPONSE DUE DATE: ☐ (Y) Yes☒ (N) No

145

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Mr. Donald L. Gilbert
A. H. Robins Company
1405 Cummings Drive
P.O. Box 26609
Richmond, VA 23261-6609

SEP 25 1991

Dear Mr. Gilbert

Subject: VirKon S
EPA Registration No. 778-91
Your Letter Dated May 31, 1991

Your submission of storage and stability data for the subject product has completed review. The following comments apply.

The storage and stability data referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable.

The 52 week (12 months) storage and stability data at ambient room temperature (25°C) is in compliance with 40 CFR part 158.190 guidelines Ref. No. 63-17. The data satisfies the one year storage stability data requirement and is acceptable.

The product was tested up to 128 weeks and appears to be stable in available chlorine.

The data were, however, inadvertently reviewed without being assigned a MRID number. The data are being forwarded for assignment of a MRID number and the Agency will send notification when the data package is complete.

If you have any questions, please call Bill Wooge at (703) 557-1295.

Sincerely yours,



Ruth G. Douglas
Acting Product Manager (32)
Antimicrobial Program Branch
Registration Division (H7504C)

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

DP BARCODE: D165117

CASE: 001751
SUBMISSION: S397319

DATA PACKAGE RECORD
BEAN SHEET

DATE: 06/14/91
Page 1 of 1

* * * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: REGISTRATION ACTION: 345 TECH-FORMULA CHANGE AMND
CHEMICALS: 063604 Potassium peroxymonosulfate 20.4000%
013905 Sodium chloride 01.5000%

ID#: 000778-00091 VIRKON S
COMPANY: 000778 A. H. ROBINS COMPANY INC
PRODUCT MANAGER: 32 WALTER FRANCIS 703-557-3964 ROOM: CM2 711-E
PM TEAM REVIEWER: RUTH DOUGLAS 703-557-3842 ROOM: CM2 711G
RECEIVED DATE: 06/04/91 DUE OUT DATE: 09/02/91

* * * DATA PACKAGE INFORMATION * * *

DP BARCODE: 165117 EXPEDITE: N DATE SENT: 06/14/91 DATE RET.: / /
CHEMICAL: 063604 Potassium peroxymonosulfate
DP TYPE: 001 Submission Related Data Package
ADMIN DUE DATE: 07/29/91 CSF: Y LABEL: Y
ASSIGNED TO DATE IN DATE OUT
DIV : RD / / / /
BRAN: RSB / / / /
SECT: PCRS / / / /
REVR : / / / /
CONTR: / / / /

* * * DATA REVIEW INSTRUCTIONS * * *

REVIEW STABILITY DATA.

* * * ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION * * *

DP BC	BRANCH/SECTION	DATE OUT	DUE BACK	INS	CSF	LABEL
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Product Chemistry Review
RSB

EPA Reg. No. or File Symbol 778-91
Data Division Received 6-4-91
Products Manager No. 32 (Francis)
Product Name Virkon S
Company Name A. H. Robbins Co., Inc.

100.0

Comments:

Enclosed 52 week (12 months) storage and stability data at ambient room temperature 25°C is in compliance with 40 CFR part 158.190 Guidelines Ref. No. 63-17. It satisfies one year storage stability data requirement and is acceptable. Product was tested up to 128 weeks and appears to be stable in available chlorine.

Note to PM
This date does not have MRED number.

Anne Skopars
6-21-91

A. H. Robins Company
1405 Cummings Drive
P. O. Box 26609
Richmond, Virginia 23261-6609
Cable Robinter/Telex 828-370
Telephone (804) 257-2000

A-H-ROBINS

Mr. Walter C. Francis
Product Manager (32)
U.S. Environmental Protection
Agency
Antimicrobial Programs Branch
Registration Division (H-7504C)
Washington, DC 20460

May 31, 1991

Re: EPA Registration 778-91
Submission of Stability for
the Product VirKon S
(Disinfectant)

Dear Mr. Francis:

VirKon S is approved by EPA as a broad spectrum disinfectant.

The A. H. Robins company have conducted the stability on VirKon S in addition to what was in the original submission. All work was done at 25 degrees Centigrade.

The following is enclosed in triplicate:

- 1) 68-week stability for VirKon S Lot 81109-73 (marketed material) showing the product is stable.
- 2) 68-week stability for VirKon S Lot 81109-74 (marketed material) showing the product is stable.

The stability of the above two lots is continuing.

In addition to the above, I am submitting other stability work that was accomplished with the product VirKon S without the color and perfume:

- 3) 128-week stability for VirKon S lot 03809160B (in the marketed container) showing the product is stable.
- 4) 104-week stability for VirKon S lot 02809160B (in the marketed container) showing the product is stable.
- 5) 128-week stability for VirKon S lot 01809160B (in the marketed container) showing the product is stable.

Mr. Walter C. Francis
May 31, 1991
Page 2

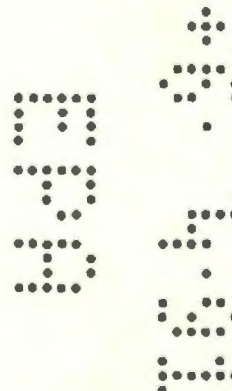
6) 52-week stability for VirKon S lost 01809160A (in the marketed container) showing the product is stable.

Please call me at (804) 257-2035 if there are any questions.

Sincerely yours,

Donald L. Gilbert

Donald L. Gilbert, B.S., M.B.A.
Director, Regulatory Affairs and
Product Development
Special Products Division





Antec
International



ACCEPTED

OCT 26 1990

Under the Federal Insecticide, Fungicide, and
Rodenticide Act, 1947, and for the
pesticide registered under
EPA Reg. No. 778-91

VirKon® S

BROAD SPECTRUM DISINFECTANT

For Use in Cleaning and Disinfecting Industrial
Animal and Agricultural Facilities

EFFECTIVE AGAINST:

BACTERIA	VIRUSES OF	FUNGI
Streptococcus pyogenes Campylobacter pyloridis Klebsiella pneumoniae Escherichia coli Salmonella typhimurium Salmonella choleraesuis Pseudomonas aeruginosa Staphylococcus aureus Staphylococcus epidermidis Mycoplasma gallisepticum	Newcastle Disease Infectious Bronchitis Infectious Bursal Disease Avian Laryngotracheitis Avian Influenza Marek's Disease	Aspergillus flavus Aspergillus fumigatus Candida albicans

ACTIVE INGREDIENTS

Potassium peroxymonosulfate.....20.4%
Sodium Chloride.....1.5%

INERT INGREDIENTS.....78.1%

TOTAL.....100.0%

Equivalent to 9.75% Available Chlorine

KEEP OUT OF REACH OF CHILDREN

DANGER:

See Back Panel for Additional Precautions

11 lbs (5kg) Net Weight

DISTRIBUTED BY

AGRI-BIO®

Agri-Bio Corp., a subsidiary of A.H. Robins Company,
966 Dorsey St, Gainesville, GA 30501, phone 1-800-AGRI-BIO
(247-4246)

In Georgia call collect 404-536-0111

VIRKON S is a registered trademark of and manufactured
by Antec International Limited U.S. Patent No: 4822512

Virkon S

BROAD SPECTRUM DISINFECTANT

VIRKON S is effective against numerous microorganisms affecting animals: viruses, gram positive and gram negative bacteria, fungi (molds and yeasts), and mycoplasma. Efficacy was determined in the presence of hard water and organic material.

CONTROLS

Viruses of - Newcastle Disease, Infectious Bronchitis, Infectious Bursal Disease, Laryngotracheitis, Avian Influenza, and Marek's Disease.

Fungi (molds and yeasts) - *Aspergillus flavus*, *Aspergillus fumigatus*, and *Candida albicans*.

Bacteria - *Streptococcus pyogenes*, *Campylobacter pyloridis*, *Klebsiella pneumoniae*, *Escherichia coli*, *Salmonella typhimurium*, *Salmonella choleraesuis*, *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Staphylococcus epidermidis*, *Mycoplasma gallisepticum*.

DIRECTIONS FOR USE

Federal law prohibits use of this product in a manner inconsistent with its labeling.

This powder formula is easily diluted for use in manual or machine operations.

VIRKON S is recommended for use in hatcheries, chicken houses, and processing plants.

HATCHERIES: **VIRKON S** at 1% is generally suitable for cleaning and disinfecting hatching, setters, evaporative coolers, humidifying systems, ceiling fans, chicken houses, transfer trucks, trays, and plastic chick boxes (use 2% for *Mycoplasma*, *Aspergillus flavus*, and *Aspergillus fumigatus*).

BROILER/BREEDER HOUSES: Following removal of chickens, feed, and water troughs, remove manure and litter and spray floors and side walls with **VIRKON S** at 1%. Thoroughly wash waterers and feeders with a 1% solution of **VIRKON S** (use 2% for *Mycoplasma*, *Aspergillus flavus*, and *Aspergillus fumigatus*). After contact for 10 minutes, rinse with potable water. Do not use to house poultry or employ equipment until treatment has dried.

PROCESSING PLANTS: For disinfecting and cleaning walls, ceilings, and floors spray at a dilution of 1%.

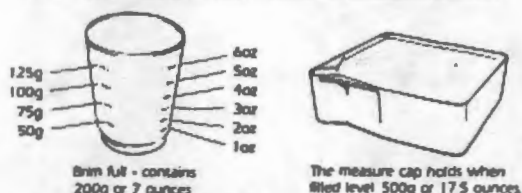
Virkon S is recommended for use in fogging (wet misting) operations as an adjunct either preceding or following regular cleaning and disinfecting procedures. **Virkon S** at 1-2% is suitable. Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions.

For air sanitizing: **Virkon S** at 1-2%; fog the atmosphere until surfaces are moist; allow at least 2 hours before entering area that has been fogged.

VirKon S

DILUTION CHART

QUANTITY OF FINAL SOLUTION	1% SOLUTION	2% SOLUTION
American		
1 gallon	1.3 ounces	2.7 ounces
10 gallons	13.4 ounces	26.7 ounces
50 gallons	66.8 ounces	133.5 ounces
Metric		
10 liters	100 grams	200 grams
50 liters	500 grams	1000 grams
200 liters	2 kgs	4 kgs



FOR DISINFECTING use a rate of 7.5 gallons/1000 sq. ft.
For CLEANING AND DISINFECTING use a rate of 15 gallons/1000 sq. ft.

STORAGE AND DISPOSAL - Store in a cool, dry place in tightly closed container. Always replace lid after use. Wash empty container thoroughly and dispose of in trash.

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals - DANGER, Corrosive. Causes skin burns and irreversible eye damage. Harmful if swallowed, absorbed through skin, or inhaled. Do not get in eyes, on skin, or on clothing. Wear protective clothing and rubber gloves. Avoid breathing dust. Wear goggles, face shield, or safety glasses. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

Practical Treatment

IF IN EYES: Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes. Get prompt medical attention.

IF ON SKIN: Wash with plenty of soap and water. Get medical attention if irritation persists.

IF INHALED or symptoms of coughing, choking, or wheezing are troublesome, remove to fresh air and seek medical attention.

IF SWALLOWED: Drink promptly a large quantity of water. Avoid alcohol. Get immediate medical attention.

NOTICE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

Manufactured for

Agh-Bio Corporation, 966 Dorsey Street, Gainesville, Georgia 30501 U.S.A.

EPA Reg. No. 778-91-63690

EPA Est. No. 62432-EN-001



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

618642
7592077

SEP 4 1992

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

Mr. Richard J. Otten
PHOENIX REGULATORY ASSOCIATES, LTD.
21525 Ridgetop Circle, #240
Sterling, VA. 22170

Agent for: ANTEC INTERNATIONAL LTD.
Chilton Industrial Estate
Sudbury, Suffolk CO10 6XD
ENGLAND

Subject: Transfer of Pesticide Registrations From
Company Number 778 to 62432

Dear Mr. Otten:

Pursuant to your request in your letter and transfer agreement of June 11, 1992 (rec'd 8/18/92), we have approved the transfer of the following registration from A.H. ROBINS COMPANY, INC., company number 778, to ANTEC INTERNATIONAL LTD., company number 62432.

The effective date of this change is August 27, 1992.

<u>Registered Products</u>	<u>Common Chemical Name</u>	<u>Old EPA Reg. No.</u>	<u>New EPA Reg. No.</u>
Virkon S	Potassium Peroxy- monosulfate	778-91	62432-1

The effective date of issuance of the new EPA registration number is August 27, 1992. You should indicate the new company designation and new EPA Reg. No. on the labeling at the next printing. If you intend to use the labels which currently appear on the transferor's product after the effective date of the transfer, you must maintain complete and accurate records which identify by batch number, lot number or other suitable description the quantities of such product bearing the transferor's label. Each container or package bearing the transferor's label which is released after the effective date of product registration transfer, must be clearly and accurately marked with the batch number, lot number or other descriptive designation used to identify the product in your records.



You are required to contact your local EPA Regional Office to determine what effect this transfer of pesticide registrations has on the pesticide production establishment registration.

It will not be necessary to submit labeling for review if the only changes are in the company designation and the EPA Reg. No. Other changes in the product and/or labeling may require EPA review and approval prior to initiation. In any correspondence on these products always refer to the U.S. EPA Reg. No. listed above.

The transferred registration will have the same status under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, 7 USC 136 et seq., as they had prior to the approval of this transfer.

When registrations are transferred from one company to a second company, all restrictions, data requirements, conditions (suspensions), and deadlines existing on the registrations are transferred with the registrations. The new company is responsible for adhering to or complying with all such restrictions, etc. on the acquired products.


In regard to deadlines, the transferee company is responsible for submitting all required data according to the schedules already established for the acquired products. Failure to do so will result in the issuance of a Notice of Intent to Suspend. Requests from transferee companies for additional time to submit because they acquired the registration(s) after the 3(c)(2)(B) request was issued will not be granted. If a transferee company has other valid reasons for delays in the testing which were clearly outside of their control, then such requests for time extensions will be considered in accordance with the established procedures. Transfers occurring while a 3(c)(2)(B) request is being issued or during the 90-day response time are subject to the same conditions expressed above.

Registration is in no way to be construed as an endorsement or approval of these products by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with FIFRA.

Furthermore, the transfer of the subject registrations is approved under the condition that the annual maintenance fee obligation has been fully satisfied. The maintenance fee is determined based solely on the total number of active sec. 3 and sec. 24(c) registrations held by the transferor. If the annual maintenance fee has not been fully satisfied, the transferee and transferor will be notified to comply within a specified time period or the affected registrations may be cancelled.

By copy of this letter we are informing A.H. ROBINS COMPANY, INCORPORATED of these changes.

Sincerely,


James A. Tompkins
Acting Section Head for
Administrative Processing Section
Registration Support Branch
Registration Division (H7505C)

cc: A.H. ROBINS COMPANY, INCORPORATED

Reviewer ID FiveSubmission No. S397029

Data Package No. _____

CODING FORM FOR APPLICATIONS FOR REGISTRATION/AMENDMENTS

File Symbol/Reg. No. 778-91 PM 32 Action Code _____☐ 10 Descriptor (Amend/Resubmissions only) **COPY OF LAST STAMPED LABEL**☒ 3 Intrastate Call-in ☐ (Y) Yes ☐ (N) No ☐ 15 Child-resistant Packaging ☐ (C) Certification ☐ (S) Service Person☐ 20 Registration Type: ☐ (1) Conditional ☐ (2) Unconditional ☐ (R) Non-residential Use Only ☐ (N) Not-Applicable☒ 25 Proposed Classification: ☐ (R) Restricted ☐ (G) General ☐ 30 Final Classification: ☐ (R) Restricted ☐ (N) Not Classified☐ 35 Date on Application: 01 29 91 ☐ 04 EPA Received Date: 06 06 91 ☐ 40 Date Received by PM: 06 06 91
MO DAY YR MO DAY YR MO DAY YR☐ 80 Method of Support: ☐ (1) Cite-All ☐ (6) Owner Submission ☐ (4) Not Applicable ☒ (7) Total Submission ☒ (5) Not Submitted ☐ (8) Selective Method

Reviewers Requested:

CH

EF

PL

DEB

NDEB

TB

EEB

EFGB

DATE SENT	DUE DATE	DATE RETURNED	RESPONSE CODE	RESPONSE DATE

☐ 115 FINAL Response ACTION Code 30☐ 120 Response JUN 6 1991
MO DAY YR75-DAY RESPONSE DUE DATE: ☐ (Y) Yes ☐ (N) No

MEMORANDUM
OF CALL

Previous editions usable

TO:

V. Deutch



YOU WERE CALLED BY-



YOU WERE VISITED BY-

Geo. Paganos

OF (Organization)



PLEASE PHONE ▶



FTS



AUTOVON

546-8427



WILL CALL AGAIN



IS WAITING TO SEE YOU



RETURNED YOUR CALL



WISHES AN APPOINTMENT

MESSAGE

778-91

Wants a copy of the
last stamped approved
label

RECEIVED BY

Label

DATE

1-29-91

TIME

3:20

Mailed to Paylanos Assoc.
1338 L St. S.W.
D.C. 20024

mm
th

Reviewer ID 5
Submission No. 5381847
Data Package No. D155614

CODING FORM FOR APPLICATIONS FOR REGISTRATION/AMENDMENTS

File Symbol/Reg. No. 778-91 PM 32 Action Code 310

10 Descriptor (Amend/Resubmissions only) Fogging Use

5 Intrastate Call-in ☐ (Y) Yes 15 Child-resistant Packaging ☐ (C) Certification
☐ (N) No ☐ (S) Service Person

20 Registration Type: ☐ (1) Conditional ☐ (2) Unconditional ☐ (R) Non-residential Use Only
☐ (N) Not-Applicable

25 Proposed Classification: 30 Final Classification:
☐ (R) Restricted ☐ (R) Restricted
☐ (G) General ☐ (N) Not Classified

35 Date on Application: 082990 04 EPA Received Date: 090490 40 Date Received by PM: 091190
MO DAY YR MO DAY YR MO DAY YR

80 Method of Support:
☐ (1) Cite-All ☐ (6) Owner Submission
☐ (4) Not Applicable ☐ (7) Total Submission
☐ (5) Not Submitted ☐ (8) Selective Method

Reviewers Requested:	DATE SENT	DUE DATE	DATE RETURNED	RESPONSE CODE	RESPONSE DATE
CH					
EF					
PL					
DEB					
NDEB					
TB					
EEB					
EFGB					

115 FINAL Response 38 120 Response OCT 26 1990
ACTION Code 38 MO DAY YR

75-DAY RESPONSE DUE DATE: ☐ (Y) Yrs ☐ (N) No

MC
160

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

OCT 26 1990

Mr. Donald L. Gilbert
Research & Development and
Regulatory Affairs
A.H. Robins Company
1405 Cummings Drive
P.O. Box 26609
Richmond, VA 23261-6609

Dear Mr. Gilbert:

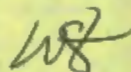
Subject: VirKon S
EPA Registration No. 778-91
Your Amendment Dated August 29, 1990

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable. A stamped copy is enclosed for your records.

Submit five copies of the finished label.

If you have any questions, please contact Arvella Farmer at (703) 557-6939.

Sincerely yours,



Walter C. Francis
Acting Product Manager (32)
Antimicrobial Program Branch
Registration Division (H7505c)

Enclosure

54055:I:A-4/A-29/A-118:WP5.0:CONCURRENCESsk:KENCO:10/14/90:DP:th:de

SYMBOL							
SURNAME							
DATE							



Antec
International



ACCEPTED

OCT 26 1990

Disinfectant, Antiseptic, and
Rodenticide Act, as amended, for the
pesticide registered under
EPA Reg. No. 778-91

VirKon[®] S

BROAD SPECTRUM DISINFECTANT

For Use in Cleaning and Disinfecting Industrial
Animal and Agricultural Facilities

EFFECTIVE AGAINST:

BACTERIA	VIRUSES OF	FUNGI
Streptococcus pyogenes Campylobacter pyloridis Klebsiella pneumoniae Escherichia coli Salmonella typhimurium Salmonella choleraesuis Pseudomonas aeruginosa Staphylococcus aureus Staphylococcus epidermidis Mycoplasma gallisepticum	Newcastle Disease Infectious Bronchitis Infectious Bursal Disease Avian Laryngotracheitis Avian Influenza Marek's Disease	Aspergillus flavus Aspergillus fumigatus Candida albicans

ACTIVE INGREDIENTS

Potassium peroxymonosulfate.....20.4%
Sodium Chloride.....1.5%

INERT INGREDIENTS.....78.1%
TOTAL.....100.0%

Equivalent to 9.75% Available Chlorine

KEEP OUT OF REACH OF CHILDREN

DANGER:

See Back Panel for Additional Precautions

11 lbs (5kg) Net Weight

DISTRIBUTED BY

AGRI-BIO[®]

Agri-Bio Corp., a subsidiary of A.H. Robins Company,
966 Dorsey St, Gainesville, GA 30501, phone 1-800-AGRI-BIO
(247-4246)

In Georgia call collect 404-536-0111

VIRKON S is a registered trademark of and manufactured
by Antec International Limited U.S. Patent No: 4822512

VirKon S

BROAD SPECTRUM DISINFECTANT

VIRKON S is effective against numerous microorganisms affecting animals: viruses, gram positive and gram negative bacteria, fungi (molds and yeasts), and mycoplasma. Efficacy was determined in the presence of hard water and organic material.

CONTROLS

Viruses of - Newcastle Disease, Infectious Bronchitis, Infectious Bursal Disease, Laryngotracheitis, Avian Influenza, and Marek's Disease.

Fungi (molds and yeasts) - *Aspergillus flavus*, *Aspergillus fumigatus*, and *Candida albicans*.

Bacteria - *Streptococcus pyogenes*, *Campylobacter pylindas*, *Klebsiella pneumoniae*, *Escherichia coli*, *Salmonella typhimurium*, *Salmonella choleraesuis*, *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Staphylococcus epidermidis*, *Mycoplasma gallisepticum*.

DIRECTIONS FOR USE

Federal law prohibits use of this product in a manner inconsistent with its labeling.

This powder formula is easily diluted for use in manual or machine operations.

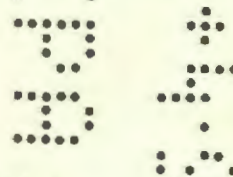
VIRKON S is recommended for use in hatcheries, chicken houses, and processing plants.

HATCHERIES: **VIRKON S** at 1% is generally suitable for cleaning and disinfecting hatcheries, setters, evaporative coolers, humidifying systems, ceiling fans, chicken houses, transfer trucks, trays, and plastic chick boxes (use 2% for *Mycoplasma*, *Aspergillus flavus*, and *Aspergillus fumigatus*).

BROILER/BREEDER HOUSES: Following removal of chickens, feed, and water troughs, remove manure and litter and spray floors and side walls with **VIRKON S** at 1%. Thoroughly wash waterers and feeders with a 1% solution of **VIRKON S** (use 2% for *Mycoplasma*, *Aspergillus flavus*, and *Aspergillus fumigatus*). After contact for 10 minutes, rinse with potable water. Do not use to house poultry or employ equipment until treatment has dried.

PROCESSING PLANTS: For disinfecting and cleaning walls, ceilings, and floors spray at a dilution of 1%.

Virkon S is recommended for use in fogging (wet misting) operations as an adjunct either preceding or following regular cleaning and disinfecting procedures. **Virkon S** at 1-2% is suitable. Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions.



For air sanitizing: **Virkon S** at 1-2%; fog the atmosphere until surfaces are moist; allow at least 2 hours before entering area that has been fogged.

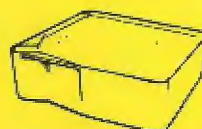
VirKon S

DILUTION CHART

QUANTITY OF FINAL SOLUTION	1% SOLUTION	2% SOLUTION
American		
1 gallon	1.3 ounces	2.7 ounces
10 gallons	13.4 ounces	26.7 ounces
50 gallons	66.8 ounces	133.5 ounces
Metric		
10 liters	100 grams	200 grams
50 liters	500 grams	1000 grams
200 liters	2 kgs	4 kgs



Brim full - contains 200g or 7 ounces



The measure cap holds when filled level 500g or 17.5 ounces.

FOR DISINFECTING use a rate of 7.5 gallons/1000 sq. ft.
For CLEANING AND DISINFECTING use a rate of 15 gallons/1000 sq. ft.

STORAGE AND DISPOSAL - Store in a cool, dry place in tightly closed container. Always replace lid after use. Wash empty container thoroughly and dispose of in trash.

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals - DANGER, Corrosive. Causes skin burns and irreversible eye damage. Harmful if swallowed, absorbed through skin, or inhaled. Do not get in eyes, on skin, or on clothing. Wear protective clothing and rubber gloves. Avoid breathing dust. Wear goggles, face shield, or safety glasses. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

Practical Treatment

IF IN EYES: Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes. Get prompt medical attention.

IF ON SKIN: Wash with plenty of soap and water. Get medical attention if irritation persists.

IF INHALED or symptoms of coughing, choking, or wheezing are troublesome, remove to fresh air and seek medical attention.

IF SWALLOWED: Drink promptly a large quantity of water. Avoid alcohol. Get immediate medical attention.

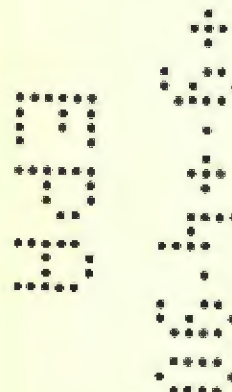
NOTICE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

Manufactured for

Agri-Bio Corporation, 966 Dorsey Street, Gainesville, Georgia 30501 U.S.A.

EPA Reg. No. 77B-91-63690.

EPA Est. No. 62432-EN-001



DP BARCODE: D155614

CASE: 001751
SUBMISSION: S381847

DATA PACKAGE RECORD
BEAN SHEET

DATE: 09/12/90
Page 1 of 1

* * * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: REGISTRATION ACTION: TECHNICAL - ADDED "ME TOO" USE AMENDMENT
CHEMICAL: 013905 Sodium chloride
ID#: 000778-00091 VIRKONS
COMPANY: 000778 A. H. ROBINS COMPANY, INC.
PRODUCT MANAGER: 32 WALTER FRANCIS 703-557-3964 ROOM: CM#2 711E
PM TEAM REVIEWER: WALTER FRANCIS 703-557-3964 ROOM: CM#2 711E
RECEIVED DATE: 09/04/90 DUE OUT DATE: 12/03/90

* * * DATA PACKAGE INFORMATION * * *

DP BARCODE: 155614 EXPEDITE: N DATE SENT: 09/12/90 DATE RET.: / /
DP TYPE: 001 Submission Related Data Package
ADMIN DUE DATE: 10/27/90 CSF: Y LABEL: Y
ASSIGNED TO DATE IN ASSIGNED TO DATE IN
DIV : RD / / REVR : WCAMPBEL / /
BRAN: AB / / CONTR: / /
SECT: EETES / /

* * * DATA PACKAGE REVIEW INSTRUCTIONS * * *

Please review the additional use for fogging (misting).

THERE ARE NO ADDITIONAL DATA PACKAGE RECORDS

Accepted w/o Comment.
WEC
9/27/90

DP BARCODE: D155614

CASE: 001751
SUBMISSION: S381847

DATA PACKAGE RECORD
BEAN SHEET

DATE: 09/17/90
Page 1 of 1

* * * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: REGISTRATION ACTION: TECHNICAL - ADDED "ME TOO" USE AMENDMENT
CHEMICAL: 013905 Sodium chloride
ID#: 000778-00091 VIRKONS
COMPANY: 000778 A. H. ROBINS COMPANY, INC.
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PM TEAM REVIEWER: WALTER FRANCIS 703-557-3964 ROOM: CM#2 711E
RECEIVED DATE: 09/04/90 DUE OUT DATE: 12/03/90

* * * DATA PACKAGE INFORMATION * * *

DP BARCODE: 155614 EXPEDITE: N DATE SENT: 09/12/90 DATE RET.: / /
DP TYPE: 001 Submission Related Data Package
ADMIN DUE DATE: 10/27/90 CSF: Y LABEL: Y
ASSIGNED TO DATE IN ASSIGNED TO DATE IN
DIV : RD / / REVR : EMITCHEL / /
BRAN: AB / / CONTR: / /
SECT: EETES / /

* * * DATA PACKAGE REVIEW INSTRUCTIONS * * *

Please review the additional use for fogging (misting).

* * * ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION * * *

DP BC	BRANCH	DATE OUT	DUE BACK	INS	CSF	LABEL
155631	AB	09/12/90	10/27/90	Y	Y	Y

EFFICACY EVALUATION AND TECHNICAL MANAGEMENT SECTION
EFFICACY REVIEW - I

Antimicrobial Program Branch

IN 09-04-90

OUT 09-13-90

Reviewed By

Emily H. Mitchell
Emily H. Mitchell

WEC
10/1/90

Date 09-13-90

EPA Reg. No. or File Symbol 778-91

EPA Petition or EUP No. None

Date Division Received 09-12-90

Type Product(s) General Disinfectant

Data Accession No.(s) _____

Product Mgr. No. PM 32 (Francis)

Product Name(s) VIRKON® S

Company Name(s) A. H. Robins Company, Inc.

Submission Purpose Label Amendment

Chemical & Formulation Powder

Active Ingredient(s):

Potassium peroxymonosulfate	<u>8</u>
Sodium Chloride	20.4%
	1.5%

EFFICACY EVALUATION AND TECHNICAL MANAGEMENT SECTION
EFFICACY REVIEW - II

Antimicrobial Program Branch

EPA Reg. No. or File Symbol 778-91
Date Division Received 09-12-90
Data Accession No.(s) _____
Product Manager No. PM 32 (Francis)
Product Name VIRKON® S
Company Name A. H. Robins Company, Inc.

202.0 Recommendations

203.0 Labeling

The fogging application claim as a adjunct is an acceptable label claim.

No adverse comments on the new label.

TO PRODUCT MANAGER

DATE:

32, Mr. Francis
9-7-90

FAST - TRACK ACTION

This action has been determined to be a fast-track action by the feps and must be entered in the OLTS using one of the following codes:

- 160 - Application for "me-too" registration
- 170 - Application for registration - old chemical - "Me-too" with additional use.
- 300 - Amendment - label revision - administrative (no data required).
- 305 - Amendment - label revision - data required does not need HED/EFED review.
- 310 - Amendment - added "me-too" Use - no HED/EFED review needed.
- 345 - Formula change - no HED/EFED review required.

09/07/90

Product Name: VIRKON-S
Company Name: A. H. ROBINS COMPANY
Application No.: 128573
EPA Reg. No.: 778-91
EPA Receipt Date: 09/04/90

Subject: Front End Screen for an Amendment

Dear Sir or Madam:

Your application for registration has been received by the Office of Pesticide Programs and has passed a preliminary screen for completeness. It will be placed in line for review to determine its acceptability. The application will be processed in chronological order of receipt.

Although the 1988 FIFRA amendments mandate EPA to review applications for expedited registration or amendments within 90 days, this turnaround time will not be met immediately due to the backlog of applications received before December 24, 1988. However, EPA is increasing human and automated resources and making necessary procedural changes in order to eliminate the backlog and to meet the 90-day response time as soon as possible.

If you have any questions, you may contact Jeff Kempter, Product Manager 32, at (703)-557-3964.

Sincerely,

James White

for

Team Leader
Front End Processing Staff
Registration Support Branch
Registration Division (H7504C)

*H7504C
James
9-7-90*



United States Environmental Protection Agency
Office of Pesticide Programs (TS-767)
Washington, DC 20460

OPP Identifier Number

128573

Application for Pesticide: ☐ Registration
☒ Amendment

Section I

Company/Product Number 778-91	2. Date August 29, 1990	3. Product Manager Walter Francis (32)	4. Proposed Classification <input checked="" type="checkbox"/> General <input type="checkbox"/> Restricted
----------------------------------	----------------------------	---	---

5. Name and Address of Applicant (Include ZIP Code)

A. H. Robins Company
1405 Cummings Drive
P.O. Box 26609
Richmond, Virginia 23261-6609

☐ Check if this is a new address

6. Product Name
VIRKON-S

Section II - Amendment Information

1. Subject <input type="checkbox"/> Resubmission in response to Agency letter <input type="checkbox"/> Final printed label in response to Agency letter <input checked="" type="checkbox"/> Other (explain below)	Date of Letter
--	----------------

PLACE FOGGING (MISTING) ON APPROVED LABEL

Section III

1. Material This Product Will Be Packaged In		2. Type of Container	
Child-Resistant Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes," Unit package wgt No. per container	Water-Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes," Package weight No. per container	<input checked="" type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify)
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) of Retail Container	
5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On material accompanying product		6. Manner in Which Label Is Affixed To Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Other (Specify) <input checked="" type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled	

Section IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application).		
Name Donald L. Gilbert		
Title Director, Product Development and Regulatory Affairs, Special Products Division	Telephone No. (Include Area Code) (804) 257-2035	
6. Date Application Received (Stamped)		
<p>Certification</p> <p>I certify that the statements I have made on this form and all attachments thereto are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.</p>		
2. Signature 	3. Title Director, Product Development and Regulatory Affairs	
4. Typed Name Donald L. Gilbert	5. Date Signed 8-29-90	

Paperwork Reduction Act Notice and Instructions

Paperwork Reduction Act Notice

Public reporting burden for this collection of information is estimated to average of 0.85 hours per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503.

Instructions

General

This form is to be used for all applications for new and amended registrations for pesticide products.

In order to process an application for new registration submitted on this form, the following material must accompany the application:

1. Offer to Pay Statement (EPA Form 8570-22, -23, or -24). (If not exempted by 40 CFR 162.9-1(b).)
2. Confidential Statement of Formula (EPA Form 8570-4).
3. Five copies of draft labeling.
4. Three copies of any data submitted.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8 1/2 x 11 inch paper or as a mockup of the proposed label. If prepared as a mockup it should be constructed in such a way as to facilitate storage in an 8 1/2 x 11 inch file. Mockup labels significantly smaller than 8 1/2 x 11 inches should be mounted on 8 1/2 x 11 inch paper for submission.

Submission of Data - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

Specific

Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Section I, III, and IV must be completed by the applicant. For applications submitted in connection with amended registration actions, Section I, II, and IV must be completed by the applicant.

Block A - Check the appropriate action for which you are submitting this form.

Section I - This Section must be completed for both Registration and Amended Registration actions.

1. **Company/Product Number** - Insert your company number, if one has been assigned. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If application is for an amendment, insert the registration number of the product.
2. **Date** - Fill in the appropriate date.
3. **Product Manager** - If known, fill in the name and number of the Product Manager.
4. **Proposed Classification** - Specify the proposed classification for this product.
5. **Name and Address of Applicant** - The name of the firm or person and address shown in your application is the person or firm to whom registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters.

An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.

6. **Product Name** - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.

Amendment Information

Section II - This Section must be completed for all applications submitted in connection with Amended Registration.

1. **Subject of Amendment** - Check the appropriate block, and provide a brief explanation of the purpose(s) for the amendment, such as: "the addition of a site, pest, or crop"; "to change inert ingredient"; "general label revisions of precautionary statements," etc.

Packaging and Container Information

Section III - This Section must be completed for all applications submitted in connection with New Registration.

1. **Type of Packaging** - Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
2. **Type of Retail Container** - Indicate type of container in which product will be marketed.
3. **Location of Net Contents** - Specify the net contents of all retail containers for your product.
4. **Size(s) of Retail Container** - Specify the net contents of all retail containers for your product.
5. **Location of Use Directions** - Indicate the location of the use directions for your product.
6. **Manner in which label is affixed to product** - Indicate the method product labeling is attached to retail container.

Contact Point

Section IV - This Section must be completed for all Registration and Amended Registration applications.

- 1-5. Self-explanatory.
6. EPA Use Only.



United States Environmental Protection Agency
Office of Pesticide Programs (TS-767)
Washington, DC 20460

OPP Identifier Number

128573

Application for Pesticide: ☐ Registration
☒ Amendment

Section I

Company/Product Number 778-91	2. Date August 29, 1990	3. Product Manager Walter Francis (32)	4. Proposed Classification <input checked="" type="checkbox"/> General <input type="checkbox"/> Restricted
----------------------------------	----------------------------	---	---

5. Name and Address of Applicant (Include ZIP Code)

A. H. Robins Company
1405 Cummings Drive
P.O. Box 26609
Richmond, Virginia 23261-6609

☐ Check if this is a new address

6. Product Name

VIRKON-S

Section II - Amendment Information

1. Subject <input type="checkbox"/> Resubmission in response to Agency letter <input type="checkbox"/> Final printed label in response to Agency letter <input checked="" type="checkbox"/> Other (explain below)	Date of Letter
--	----------------

PLACE FOGGING (MISTING) ON APPROVED LABEL

Section III

1. Material This Product Will Be Packaged In		2. Type of Container	
Child-Resistant Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes," Unit package wgt No. per container	Water-Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes," Package weight No. per container	<input checked="" type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify)
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container	4. Size(s) of Retail Container		
5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On material accompanying product	6. Manner in Which Label Is Affixed To Product <input type="checkbox"/> Lithograph <input checked="" type="checkbox"/> Paper glued <input type="checkbox"/> Other (Specify) <input type="checkbox"/> Stenciled		

Section IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application).		
Name Donald L. Gilbert		
Title Director, Product Development and Regulatory Affairs, Special Products Division	Telephone No. (Include Area Code) (804) 257-2035	6. Date Application Received (Stamp)
<p>Certification</p> <p>I certify that the statements I have made on this form and all attachments thereto are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.</p>		
2. Signature 	3. Title Director, Product Development and Regulatory Affairs	
4. Typed Name Donald L. Gilbert	5. Date Signed 8-29-90	

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3. Five copies of draft labeling.
4. Three copies of any data submitted.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8 1/2 x 11 inch paper or as a mockup of the proposed label. If prepared as a mockup it should be constructed in such a way as to facilitate storage in an 8 1/2 x 11 inch file. Mockup labels significantly smaller than 8 1/2 x 11 inches should be mounted on 8 1/2 x 11 inch paper for submission.

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Specific

Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Section I, III, and IV must be completed by the applicant. For applications submitted in connection with amended registration actions, Section I, II, and IV must be completed by the applicant.

Block A - Check the appropriate action for which you are submitting this form.

Section I - This Section must be completed for both Registration and Amended Registration actions.

1. **Company/Product Number** - Insert your company number, if one has been assigned. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If application is for an amendment, insert the registration number of the product.
2. **Date** - Fill in the appropriate date.
3. **Product Manager** - If known, fill in the name and number of the Product Manager.
4. **Proposed Classification** - Specify the proposed classification for this product.
5. **Name and Address of Applicant** - The name of the firm or person and address shown in your application is the person or firm to whom registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters.

An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.

6. **Product Name** - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.

Amendment Information

Section II - This Section must be completed for all applications submitted in connection with Amended Registration.

1. **Subject of Amendment** - Check the appropriate block, and provide a brief explanation of the purpose(s) for the amendment, such as: "the addition of a site, pest, or crop"; "to change inert ingredient"; "general label revisions of precautionary statements," etc.

Packaging and Container Information

Section III - This Section must be completed for all applications submitted in connection with New Registration.

1. **Type of Packaging** - Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
2. **Type of Retail Container** - Indicate type of container in which product will be marketed.
3. **Location of Net Contents** - Specify the net contents of all retail containers for your product.
4. **Size(s) of Retail Container** - Specify the net contents of all retail containers for your product.
5. **Location of Use Directions** - Indicate the location of the use directions for your product.
6. **Manner in which label is affixed to product** - Indicate the method product labeling is attached to retail container.

Contact Point

Section IV - This Section must be completed for all Registration and Amended Registration applications.

- 1-5. Self-explanatory.
6. EPA Use Only.

United States Environmental Protection Agency
Office of Pesticide Programs (TS-767)
Washington, DC 20460

OPP Identifier Number

128573



Application for Pesticide:

☐ Registration
☒ Amendment

Section I

1. Company/Product Number
110-22

2. Date
August 29, 1990

3. Product Manager
Walter Francis (32)

4. Proposed Classification
☒ General ☐ Restricted

5. Name and Address of Applicant (Include ZIP Code)

A. H. Robins Company
1405 Cummings Drive
P.O. Box 25609
Richmond, Virginia 23261-6609

☐ Check if this is a new address

6. Product Name

VIRACOR-S

Section II - Amendment Information

1. Subject
☐ Resubmission in response to Agency letter
☐ Final printed label in response to Agency letter
☒ Other (explain below)

Date of Letter

PLACE FOGGING (MISTING) ON APPROVED LABEL

Section III

1. Material This Product Will Be Packaged In

Child-Resistant Packaging
☒ Yes ☐ No

Unit Packaging
☐ Yes ☒ No
 If "Yes,"
 Unit package wgt No. per container

Water-Soluble Packaging
☐ Yes ☒ No
 If "Yes,"
 Package weight No. per container

2. Type of Container
☒ Metal
☐ Plastic
☐ Glass
☐ Paper
☐ Other (Specify)

3. Location of Net Contents Information
☒ Label ☐ Container

4. Size(s) of Retail Container

5. Location of Label Directions
☒ On Label
☐ On material accompanying product

6. Manner in Which Label Is Affixed To Product
☐ Lithograph
☒ Paper glued
☐ Stenciled
☐ Other (Specify)

Section IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application).

Name
Donald L. Gilbert

Title
Director, Product Development and Regulatory Affairs, Special Products Division

Telephone No. (Include Area Code)
(804) 257-2035

6. Date Application Received (Stamped)

Certification
 I certify that the statements I have made on this form and all attachments thereto are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

2. Signature
Donald L. Gilbert

3. Title
Director, Product Development and Regulatory Affairs

4. Typed Name
Donald L. Gilbert

5. Date Signed
8-29-90

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Block A - Check the appropriate action for which you are submitting this form.

Section I - This Section must be completed for both Registration and Amended Registration actions.

1. **Company/Product Number** - Insert your company number, if one has been assigned. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If application is for an amendment, insert the registration number of the product.
2. **Date** - Fill in the appropriate date.
3. **Product Manager** - If known, fill in the name and number of the Product Manager.
4. **Proposed Classification** - Specify the proposed classification for this product.
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6. **Product Name** - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.

Amendment Information

Section II - This Section must be completed for all applications submitted in connection with Amended Registration.

1. **Subject of Amendment** - Check the appropriate block, and provide a brief explanation of the purpose(s) for the amendment, such as: "the addition of a site, pest, or crop"; "to change inert ingredient"; "general label revisions of precautionary statements," etc.

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1. **Type of Packaging** - Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
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4. **Size(s) of Retail Container** - Specify the net contents of all retail containers for your product.
5. **Location of Use Directions** - Indicate the location of the use directions for your product.
6. **Manner in which label is affixed to product** - Indicate the method product labeling is attached to retail container.

Contact Point

Section IV - This Section must be completed for all Registration and Amended Registration applications.

- 1-5. Self-explanatory.
6. EPA Use Only.



United States Environmental Protection Agency
Office of Pesticide Programs (TS-767)
Washington, DC 20460

OPP Identifier Number

128573

Application for Pesticide: ☐ Registration ☒ Amendment

Section I

1. Company/Product Number 778-91 2. Date August 29, 1990 3. Product Manager Walter Francis (32) 4. Proposed Classification ☒ General ☐ Restricted

5. Name and Address of Applicant (Include ZIP Code)

A. H. Robins Company
1405 Cummings Drive
P.O. Box 26609
Richmond, Virginia 23261-6609

☐ Check if this is a new address

6. Product Name

VERMEX-S

Section II - Amendment Information

1. Subject ☐ Resubmission in response to Agency letter ☐ Final printed label in response to Agency letter ☒ Other (explain below) Date of Letter

PLACE FOGGING (MISTING) ON APPROVED LABEL.

Section III

1. Material This Product Will Be Packaged In Child-Resistant Packaging ☒ Yes ☐ No Unit Packaging ☐ Yes ☒ No Water-Soluble Packaging ☐ Yes ☒ No If "Yes," Unit package wgt No. per container If "Yes," Package weight No. per container 2. Type of Container ☒ Metal ☐ Plastic ☐ Glass ☐ Paper ☐ Other (Specify) 3. Location of Net Contents Information ☒ Label ☐ Container 4. Size(s) of Retail Container 5. Location of Label Directions ☒ On Label ☐ On material accompanying product 6. Manner in Which Label Is Affixed To Product ☐ Lithograph ☒ Paper glued ☐ Other (Specify) ☐ Stenciled

Section IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application).

Name Donald L. Gilbert

Title Director, Product Development and Regulatory Affairs, Special Products Division

Telephone No. (Include Area Code) (804) 257-2035

6. Date Application Received (Stamped)

Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

2. Signature

Donald L. Gilbert

3. Title Director, Product Development and Regulatory Affairs

4. Typed Name

Donald L. Gilbert

5. Date Signed 8-29-90

Paperwork Reduction Act Notice and Instructions

Paperwork Reduction Act Notice

Public reporting burden for this collection of information is estimated to average of 0.85 hours per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503.

Instructions

General

This form is to be used for all applications for new and amended registrations for pesticide products.

In order to process an application for new registration submitted on this form, the following material must accompany the application:

1. Offer to Pay Statement (EPA Form 8570-22, -23, or -24). (If not exempted by 40 CFR 162.9-1(b).)
2. Confidential Statement of Formula (EPA Form 8570-4).
3. Five copies of draft labeling.
4. Three copies of any data submitted.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8 1/2 x 11 inch paper or as a mockup of the proposed label. If prepared as a mockup it should be constructed in such a way as to facilitate storage in an 8 1/2 x 11 inch file. Mockup labels significantly smaller than 8 1/2 x 11 inches should be mounted on 8 1/2 x 11 inch paper for submission.

Submission of Data - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

Specific

Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Section I, III, and IV must be completed by the applicant. For applications submitted in connection with amended registration actions, Section I, II, and IV must be completed by the applicant.

Block A - Check the appropriate action for which you are submitting this form.

Section I - This Section must be completed for both Registration and Amended Registration actions.

1. **Company/Product Number** - Insert your company number, if one has been assigned. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If application is for an amendment, insert the registration number of the product.
2. **Date** - Fill in the appropriate date.
3. **Product Manager** - If known, fill in the name and number of the Product Manager.
4. **Proposed Classification** - Specify the proposed classification for this product.
5. **Name and Address of Applicant** - The name of the firm or person and address shown in your application is the person or firm to whom registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters.

An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.

6. **Product Name** - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.

Amendment Information

Section II - This Section must be completed for all applications submitted in connection with Amended Registration.

1. **Subject of Amendment** - Check the appropriate block, and provide a brief explanation of the purpose(s) for the amendment, such as: "the addition of a site, pest, or crop"; "to change inert ingredient"; "general label revisions of precautionary statements," etc.

Packaging and Container Information

Section III - This Section must be completed for all applications submitted in connection with New Registration.

1. **Type of Packaging** - Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
2. **Type of Retail Container** - Indicate type of container in which product will be marketed.
3. **Location of Net Contents** - Specify the net contents of all retail containers for your product.
4. **Size(s) of Retail Container** - Specify the net contents of all retail containers for your product.
5. **Location of Use Directions** - Indicate the location of the use directions for your product.
6. **Manner in which label is affixed to product** - Indicate the method product labeling is attached to retail container.

Contact Point

Section IV - This Section must be completed for all Registration and Amended Registration applications.

- 1-5. Self-explanatory.
6. EPA Use Only.

A. H. Robins Company
1405 Cummings Drive
P. O. Box 26609
Richmond, Virginia 23261-6609
Cable Robinter/Telex 828-370
Telephone (804) 257-2000

A-H-ROBINS

Mr. Walter C. Francis
Product Manager (32)
U.S. ENVIRONMENTAL PROTECTION
AGENCY
Antimicrobial Programs Branch
Registration Division (H-7504C)
Washington, DC 20460

August 29, 1990

EPA Registration: 778-91

RE: SUBMISSION OF AMENDED APPLICATION FOR REGISTRATION OF VIRKON-S
(AMENDED LABEL - DIRECTIONS FOR USE IN FOGGING APPLICATIONS)

Dear Mr. Francis:

Virkon-S is approved by EPA as a broad spectrum disinfectant. In recent days, I have been in telephone contact with Mr. Wallace Powell asking for clarification on us using Virkon-S in fogging (misting) applications. The response was that consideration can be given to labeling bearing recommendations for fogging applications of chemicals provided that directions are given limiting the application of such procedures to use as an adjunct to acceptable cleaning and disinfecting. Applications prior to manual cleaning and disinfecting operations or subsequent to such operations are considered adjuncts to such operations. Mr. Powell stated that we should file an amended label and no efficacy or other data would be required.

The following is enclosed in requesting an amendment to our approved label requesting fogging (misting):

- 1.) EPA Form 8570-1, EPA Application for Pesticide (Amendment)
- 2.) Five (5) copies of the proposed labeling.

If there are any questions, please call me at (804) 257-2035.

Sincerely yours,

Donald L. Gilbert

Donald L. Gilbert, B.S., M.B.A.
Director, Regulatory Affairs and
Product Development



VirKon S

BROAD SPECTRUM DISINFECTANT

For Use in Cleaning and Disinfecting Industrial
Animal and Agricultural Facilities

EFFECTIVE AGAINST:

BACTERIA	VIRUSES OF	FUNGI
Streptococcus pyogenes Campylobacter pyloridis Klebsiella pneumoniae Escherichia coli Salmonella typhimurium Salmonella choleraesuis Pseudomonas aeruginosa Staphylococcus aureus Staphylococcus epidermidis Mycoplasma gallisepticum	Newcastle Disease Infectious Bronchitis Infectious Bursal Disease Avian Laryngotracheitis Avian Influenza Marek's Disease	Aspergillus flavus Aspergillus fumigatus Candida albicans

ACTIVE INGREDIENTS

Potassium peroxymonosulfate 20.4%
Sodium Chloride 1.5%

INERT INGREDIENTS 78.1%

TOTAL 100.0%

Equivalent to 9.75% Available Chlorine

**KEEP OUT OF REACH OF CHILDREN
DANGER:**

See Back Panel for Additional Precautions

11 lbs (5kg) Net Weight

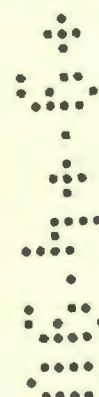
DISTRIBUTED BY

AGRI-BIO

Agri-Bio Corp., a subsidiary of A.H. Robins Company,
966 Dorsey St. Gainesville, GA 30501, phone 1-800-AGRI-BIO
(247-4246)

In Georgia call collect 404-536-0111

VIRKON S is a registered trademark of and manufactured
by Antec International Limited U.S. Patent No: 4822512



VirKon S

BROAD SPECTRUM DISINFECTANT

VIRKON S is effective against numerous microorganisms affecting animals: viruses, gram positive and gram negative bacteria, fungi (molds and yeasts), and mycoplasma. Efficacy was determined in the presence of hard water and organic material.

CONTROLS

Viruses of - Newcastle Disease, Infectious Bronchitis, Infectious Bursal Disease, Laryngotracheitis, Avian Influenza, and Marek's Disease.

Fungi (molds and yeasts) - *Aspergillus flavus*, *Aspergillus fumigatus*, and *Candida albicans*.

Bacteria - *Streptococcus pyogenes*, *Campylobacter pyloridis*, *Klebsiella pneumoniae*, *Escherichia coli*, *Salmonella typhimurium*, *Salmonella choleraesuis*, *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Staphylococcus epidermidis*, *Mycoplasma gallisepticum*.

DIRECTIONS FOR USE

Federal law prohibits use of this product in a manner inconsistent with its labeling.

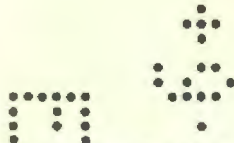
This powder formula is easily diluted for use in manual or machine operations.

VIRKON S is recommended for use in hatcheries, chicken houses, and processing plants.

HATCHERIES: **VIRKON S** at 1% is generally suitable for cleaning and disinfecting hatches, setters, evaporative coolers, humidifying systems, ceiling fans, chicken houses, transfer trucks, trays, and plastic chick boxes (use 2% for *Mycoplasma*, *Aspergillus flavus*, and *Aspergillus fumigatus*).

BROILER/BREEDER HOUSES: Following removal of chickens, feed, and water troughs, remove manure and litter and spray floors and side walls with **VIRKON S** at 1%. Thoroughly wash waterers and feeders with a 1% solution of **VIRKON S** (use 2% for *Mycoplasma*, *Aspergillus flavus*, and *Aspergillus fumigatus*). After contact for 10 minutes, rinse with potable water. Do not use to house poultry or employ equipment until treatment has dried.

PROCESSING PLANTS: For disinfecting and cleaning walls, ceilings, and floors spray at a dilution of 1%.



Virkon S is recommended for use in fogging (wet misting) operations as an adjunct either preceding or following regular cleaning and disinfecting procedures. **Virkon S** at 1-2% is suitable. Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions.

For air sanitizing: **Virkon S** at 1-2%; fog the atmosphere until surfaces are moist; allow at least 2 hours before entering area that has been fogged.

VirKon[®] S

DILUTION CHART

QUANTITY OF FINAL SOLUTION	1% SOLUTION	2% SOLUTION
American		
1 gallon	1.3 ounces	2.7 ounces
10 gallons	13.4 ounces	26.7 ounces
50 gallons	66.8 ounces	133.5 ounces
Metric		
10 liters	100 grams	200 grams
50 liters	500 grams	1000 grams
200 liters	2 kgs	4 kgs



When full - contains
200g or 7 ounces



The measure cap holds when
filled level 500g or 17.5 ounces.

FOR DISINFECTING use a rate of 7.5 gallons/1000 sq. ft.

For CLEANING AND DISINFECTING use a rate of 15 gallons/1000 sq. ft.

STORAGE AND DISPOSAL - Store in a cool, dry place in tightly closed container. Always replace lid after use. Wash empty container thoroughly and dispose of in trash.

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals - DANGER, Corrosive. Causes skin burns and irreversible eye damage. Harmful if swallowed, absorbed through skin, or inhaled. Do not get in eyes, on skin, or on clothing. Wear protective clothing and rubber gloves. Avoid breathing dust. Wear goggles, face shield, or safety glasses. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

Practical Treatment

IF IN EYES: Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes. Get prompt medical attention.

IF ON SKIN: Wash with plenty of soap and water. Get medical attention if irritation persists.

IF INHALED or symptoms of coughing, choking, or wheezing are troublesome, remove to fresh air and seek medical attention.

IF SWALLOWED: Drink promptly a large quantity of water. Avoid alcohol. Get immediate medical attention.

NOTICE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

Manufactured for

Agri-Bio Corporation, 966 Dorsey Street, Gainesville, Georgia 30501 U.S.A.

EPA Reg. No. 778-91-63690.

EPA Est. No. 62432-EN-001



Antec
International



VirKon® S

BROAD SPECTRUM DISINFECTANT

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EFFECTIVE AGAINST:

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ACTIVE INGREDIENTS

Potassium peroxymonosulfate20.4%
Sodium Chloride..... 1.5%

INERT INGREDIENTS.....78.1%

TOTAL.....100.0%

Equivalent to 9.75% Available Chlorine

KEEP OUT OF REACH OF CHILDREN
DANGER:

See Back Panel for Additional Precautions

11 lbs (5kg) Net Weight

DISTRIBUTED BY

AGRI-BIO®

Agri-Bio Corp., a subsidiary of A.H. Robins Company,
966 Dorsey St, Gainesville, GA 30501, phone 1-800-AGRI-BIO
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In Georgia call collect 404-536-0111

VIRKON S is a registered trademark of and manufactured
by Antec International Limited U.S. Patent No: 4822512

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VIRKON S is effective against numerous microorganisms affecting animals: viruses, gram positive and gram negative bacteria, fungi (molds and yeasts), and mycoplasma. Efficacy was determined in the presence of hard water and organic material.

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Viruses of - Newcastle Disease, Infectious Bronchitis, Infectious Bursal Disease, Laryngotracheitis, Avian Influenza, and Marek's Disease.

Fungi (molds and yeasts) - *Aspergillus flavus*, *Aspergillus fumigatus*, and *Candida albicans*.

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DIRECTIONS FOR USE

Federal law prohibits use of this product in a manner inconsistent with its labeling.

This powder formula is easily diluted for use in manual or machine operations.

VIRKON S is recommended for use in hatcheries, chicken houses, and processing plants.

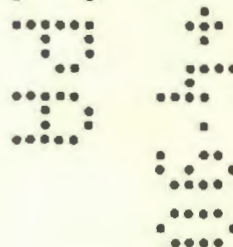
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VirKon[®]S

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Metric		
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200 liters	2 kgs	4 kgs



FOR DISINFECTING use a rate of 7.5 gallons/1000 sq. ft.
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NOTICE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

Manufactured for

Agn-Bio Corporation, 966 Dorsey Street, Gainesville, Georgia 30501 U.S.A.

EPA Reg. No. 778-91-63690

EPA Est. No. 62432-EN-001



Antec
International



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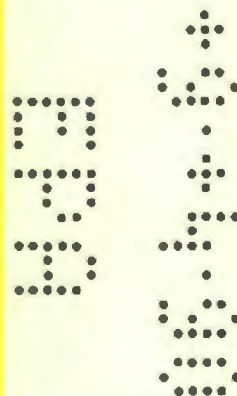
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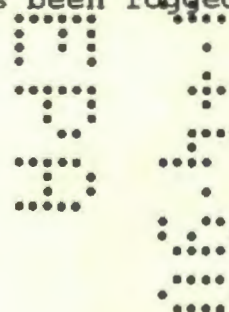
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VirKon[®] S

DILUTION CHART

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American		
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50 gallons	66.8 ounces	133.5 ounces
Metric		
10 liters	100 grams	200 grams
50 liters	500 grams	1000 grams
200 liters	2 kgs	4 kgs



Brim full - contains 200g or 7 ounces

The measure cup holds when filled level 500g or 17.5 ounces

FOR DISINFECTING use a rate of 7.5 gallons/1000 sq. ft.
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EPA Reg. No. 778-91-63690.

EPA Est. No. 62432-EN-001

RECORD OF COMMUNICATION		<input checked="" type="checkbox"/> PHONE CALL <input type="checkbox"/> DISCUSSION <input type="checkbox"/> FIELD TRIP <input type="checkbox"/> CONFERENCE <input type="checkbox"/> OTHER (SPECIFY)			
		(Record of item checked above)			
TO: Don Gilbert of A.H. Robins. (804)257-2035		FROM: Wallace Powell		DATE 8/23/90	
SUBJECT Virkon S. — EPA Reg. No. 778-91				TIME	

SUMMARY OF COMMUNICATION

In response to his questions, I told him the following (after I talked with Bill Campbell):

To send out a promotional flyer that says the product can be used for cleaning poultry buildings (no antimicrobial claims) is okay. However, if the flyer is included with the product during shipping and sale, then we want to see the flyer, and he should apply for Amendment.

To send out a flyer that says the product can be used for fogging poultry buildings or hatcheries or setters implies sanitization*, so this use would have to be approved via labeling amendment. This would be required whether the flyer would be included with the product during shipping and sale (and so would be considered to be labeling) or not (and would be considered advertizing).

I told him I'd FAX him the standard comments shown

CONCESSIONS, ACTION TAKEN OR REQUIRED

on the next page. →

(Note: Mr. Gilbert mentioned a February 1989 FDA letter that said it was okay to use the product for fogging hatcheries and setters, with the exception of table eggs.)

*Sanitization is the usual reason for fogging poultry buildings.

of closed spaces. Products of this kind are "air sanitizers" that "temporarily reduce the number of air-borne bacteria and viruses" or "temporarily reduce the danger or hazard of air-borne infection."

D-410 Fogging applications of germicides and disinfectants cannot be accepted to disinfect air or room surfaces. Thus, such label representations as "germicidal fogging," "decontamination," and "disinfectant fogging" are not acceptable, ~~and must be deleted.~~

D-411 Consideration can be given to labeling bearing recommendations for fogging applications of chemicals to sanitize surfaces, provided that clear-cut directions are given limiting the application of such procedures to use as an adjunct to acceptable manual cleaning and disinfecting of room surfaces. Applications prior to manual cleaning and disinfecting operations, or subsequent to such operations are considered as adjuncts to such operations. (The underlined wording, or very similar statements, must appear on the label text.)

D-412 The terms "sterilize," "sterilizing," and "sterilization" denote the destruction of all living organisms. Since this product, used as directed, could not be relied upon to kill all living organisms including bacterial endospores, such claims are not justified and must be deleted. No objection would be raised to replacements such as "germicidal," "disinfect," or "bactericidal" providing, of course, that the product will provide such benefits.

D-413 Drains which cannot be disassembled and manually cleaned cannot be disinfected. Therefore, claims made for such drain applications must be limited to deodorizing only.

D-414 Hard water inactivation is largely a matter of slowing down the killing time and is only of major significance in those applications where speed of kill is essential, as in restaurants for dishes, glassware, and utensils. Since no such specific recommendations are made on the label where such action is vital, the hard water claim must be deleted.

D-415 Delete all claims that the product is effective in disinfecting mattresses, upholstered furniture, pillows, or other textile materials unless data are submitted to support these claims. In lieu of this, the claims must be restricted to applications on hard, non-porous surfaces.

Record Number 262,497Reference Number 4

Input Date _____

CODING FORM FOR APPLICATIONS FOR REGISTRATION/AMENDMENTS

File Symbol/Reg. No. 778-91 PM 32 I.D.
6 Action Code 34610 Descriptor (Amend/Resubmissions only) _____5 Intrastate Call-in ☐ (Y) Yes 15 Child-resistant Packaging ☐ (C) Certification
☒ (N) No ☐ (S) Service Person20 Registration Type:☐ (1) Conditional ☒ (2) Unconditional☐ (R) Non-residential Use Only☒ (N) Not-Applicable25 Proposed Classification: 30 Final Classification:☐ (R) Restricted ☐ (R) Restricted☐ (G) General ☒ (N) Not Classified35 Date on Application:

0	3	2	7	9	0
MO		DAY		YR	

04 EPA Received Date:

0	4	0	9	9	0
MO		DAY		YR	

40 Date Received by PM

0	4	1	0	9	0
MO		DAY		YR	

80 Method of Support:☐ (1) Cite-All ☐ (6) Owner Submission☒ (4) Not Applicable ☐ (7) Total Submission☐ (5) Not Submitted ☐ (8) Selective Method

Reviewers Requested:

RD

PM

PL

CH

EF

DATE SENT	DUE DATE	DATE RETURNED

4-24-90	6-5-90	5-9-90
---------	--------	--------

RESPONSE CODE	RESPONSE DATE

108 Status: _____115 FINAL Response ACTION Code 17120 Response

0	5	1	1	9	0
MO		DAY		YR	

75-DAY RESPONSE DUE DATE: ☐ (Y) Yes☒ (N) No

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

MAY 11 1990

Donald L. Gilbert
 Director, Feed Additives
 Research & Development and Regulatory Affairs
 A.H. Robins Company
 1405 Cummings Drive
 P.O. Box 26609
 Richmond, VA 23261-6609

Subject: VirKon S
 EPA Registration No. 778-91
 Your Submission Dated March 21, 1990
 Your Supplier's Submission (on Your Behalf)
 Dated March 27, 1990

Dear Mr. Gilbert:

This is in response to submission of the Material Safety Data Sheet and chemical composition, requested in EPA letter dated March 8, 1990, for the ingredient [REDACTED]

The information referred to above (and your amendment dated January 5, 1990, for addition of coloring agent), submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable.

Sincerely,

WCF

Walter C. Francis
 Acting Product Manager (32)
 Antimicrobial Program Branch
 Registration Division (H-7504C)

Inert ingredient information may be entitled to confidential treatment

CONCURRENCES							
SYMBOL							
SURNAME	W. Powell						
DATE							



United States Environmental Protection Agency
Office of Pesticide Programs
Washington, DC 20460

Data Review Record

Confidential Business Information - Does not contain
National Security Information (E.O. 12065)

Pack Number

Date Received

1. Product Name

Vir Kon S

Chemical Name

Potassium peroxymanosulfate

2.

Identifying Number

778-91

3.

Record Number

259-814

4. Action

Code

346

5. MRID/

Accession Number

6.

Study Guideline or Narrative

Chemistry
Chemistry

7. Reference No.

4

8. Date Rec'd (EPA)

4-9-90

9. Prod/Review Mgr/DCI

Francis/Powell

10. PM/RM Team No.

32

11. Date to HED/
EFED/RD/BEAD

4-24-90

12. Proj Return Date

6-5-90

13. Date Returned
to RD/SRRD

5-9-90

Instructions

Please Review submitted information on [REDACTED]
submitted in response to EPA letter dated 3/8/90.

This Section Applies to Review of Studies Only

14. Check Applicable Box



Adverse 6(a)(2) Data (405)



Generic Data (Reregistration)(660)



Special Review Data (870)



Product Specific Data (Reregistration)(655)

16. Have any of the above studies (in whole or in part) been previously submitted for review?



Yes (Please identify the study(ies))



No

15. No. of Individual Studies
Submitted

17. Related Actions

18.

To

Type of Review

19. Reviews Also Sent to

20. Data Review Criteria

HED

Science Analysis & Coordination

Toxicology/HFA

Toxicology/IR

Dietary Exposure

Nondietary Exposure

SAC

PC

TOX/HFA

PL

TOX/IR

DEB

EA

NDE

AC

BA

A. Policy Note No. 31

☐ 1 = data which meet 6(a)(2) or
meet 3(c)(2)(B) flagging
criteria

☐ 2 = data of particular concern
from registration standard

☐ 3 = data necessary to determine
tiered testing requirements

B. Section 18

☐ 1 = data in support of section 3
in lieu of section 18

C. Inert Ingredients

☐ 1 = data in support of continued
use of List 1 inert

EFED

Ecological Effects

Environmental Fate & Groundwater

EEB

EFGWB

SRRD

Special Review

Reregistration

Generic Chemical Support

SR

RER

GSC

RD

Insecticide-Rodenticide

Fungicide-Herbicide

Antimicrobial

Product Chemistry

Precautionary Labeling

IR

FH

AM

BEAD

Economic Analysis

Analytical Chemistry

Biological Analysis

☐ Confidential Statement of Formula
(EPA Form 8570-4) Attached (Trade Secrets)

☐ Label Attached

PRODUCT CHEMISTRY Review
RSB

EPA Reg. No. or File Symbol 778-91
Date Division Received 4-9-90
Products Manager No. 32 (Francis)
Product Name Virkon S
Company Name A. H. Robin's Co., Inc.

100.0

Comments:

Enclosed chemical identity of fragrance, [REDACTED] has been reviewed and placed in your Confidential File and is acceptable.

There are no adverse comments on this submission on product chemistry.

Anna Skapers
5-8-90

Inert ingredient information may be entitled to confidential treatment

Inert ingredient and product ingredient source information may be entitled to confidential treatment

Record Number 261,813Reference Number 4

Input Date _____

CODING FORM FOR APPLICATIONS FOR REGISTRATION/AMENDMENTS

File Symbol/Reg. No. 778-91 PM 32 ^{I.D.}6 Action Code 34610 Descriptor (Amend/Resubmissions only) _____5 Intrastate Call-in ☐ (Y) Yes ☒ (N) No 15 Child-resistant Packaging ☐ (C) Certification ☐ (S) Service Person20 Registration Type:☐ (1) Conditional ☒ (2) Unconditional☒ (R) Non-residential Use Only☐ (N) Not-Applicable25 Proposed Classification: 30 Final Classification:☐ (R) Restricted ☐ (R) Restricted
☐ (G) General ☒ (N) Not Classified35 Date on Application: 04 EPA Received Date:0 3 2 1 9 0
MO DAY YR0 3 2 7 9 0
MO DAY YR40 Date Received by PM0 3 2 8 9 0
MO DAY YR80 Method of Support:☐ (1) Cite-All ☐ (6) Owner Submission
☒ (4) Not Applicable ☐ (7) Total Submission
☐ (5) Not Submitted ☐ (8) Selective Method

Reviewers Requested:

RD

PM

PL

CH

EF

DATE SENT DUE DATE DATE RETURNED

9-24-90	6-5-90	5-9-90

RESPONSE CODE RESPONSE DATE

108 Status: _____115 FINAL Response ACTION Code 17120 Response 0 5 1 1 9 0
MO DAY YR75-DAY RESPONSE DUE DATE: ☐ (Y) Yes ☒ (N) No

Inert ingredient information may be entitled to confidential treatment

Donald L. Gilbert
Director, Feed Additives
Research & Development and Regulatory Affairs
A.H. Robins Company
1405 Cummings Drive
P.O. Box 26609
Richmond, VA 23261-6609

Dear Mr. Gilbert:

The information referred to above (and your amendment dated January 5, 1990, for addition of coloring agent), submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable.

Sincerely,

Walter C. Francis
Acting Product Manager (32)
Antimicrobial Program Branch
Registration Division (H-7504C)

CONCURRENCES							
SERIAL							
SUBNAME	W. Powell						
DATE							
REAR CAMP 1300' (11279) 41.6 (11279) (11279) (11279) (11279) (11279) (11279) (11279) OFFICIAL FILE COPY							

Robert L. Miller, D.V.M.
Vice President, Office of Veterinary Medicine

A. H. Robins Company
1405 Cummings Drive
P. O. Box 26609
Richmond, Virginia 23261-6609
Cable Robinco /TWX 7109560001
Telephone (804) ~~XXX~~ 257-2879

A·H·ROBINS

Mr. Walter C. Francis
Acting Product Manager (PM-32)
Document Processing Desk
Office of Pesticide Programs (H-7504C)
U. S. Environmental Protection Agency
401 M Street, S.W.
Washington, DC 20460

March 21, 1990


Re: EPA Reg. No. 778-91
VirKon S

Dear Mr. Francis:

Reference is made to your letter of March 8, 1990, requesting additional information on the fragrance [REDACTED] in VirKon S.

The supplier, [REDACTED] has supplied the enclosed Material Safety Data Sheet. The list of specific chemicals with CAS numbers will be supplied directly to the Agency by [REDACTED]. Because of their confidentiality requirements, they will not reveal this information to anyone except a regulatory agency.

Sincerely,


R. L. Miller, D.V.M.

dhc

Enclosure

RECEIVED

MAR 27 1990

ANTIMICROBIAL BRANCH

Record Number 259,814
Reference Number 4
Input Date _____

CODING FORM FOR APPLICATIONS FOR REGISTRATION/AMENDMENTS

File Symbol/Reg. No. 778-91 PM 22 ^{I.D.} 6 Action Code 345
10 Descriptor (Amend/Resubmissions only) 41382101 (Split Review)

5 Intrastate Call-in ☐ (Y) Yes ☒ (N) No 15 Child-resistant Packaging ☐ (C) Certification ☐ (S) Service Person
20 Registration Type: ☐ (1) Conditional ☒ (2) Unconditional ☐ (R) Non-residential Use Only ☒ (N) Not-Applicable

25 Proposed Classification: ☐ (R) Restricted ☐ (G) General 30 Final Classification: ☐ (R) Restricted ☒ (N) Not Classified

35 Date on Application: 01 05 90 04 EPA Received Date: 01 12 90 40 Date Received by PM: 02 15 90
MO DAY YR MO DAY YR MO DAY YR

80 Method of Support: ☐ (1) Cite-All ☒ (4) Not Applicable ☐ (5) Not Submitted ☐ (6) Owner Submission ☐ (7) Total Submission ☐ (8) Selective Method

Reviewers Requested:

RD

PM

PL

CH

EF

DATE SENT	DUE DATE	DATE RETURNED	RESPONSE CODE	RESPONSE DATE
2-21-90	4-4-90	2-28-90		
2-21-90	4-4-90	2-28-90		

108 Status: _____

115 FINAL Response ACTION Code 11 120 Response 03 08 90
MO DAY YR

75-DAY RESPONSE DUE DATE: ☐ (Y) Yes ☒ (N) No

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

MAR 08 1990

Robert L. Miller, D.V.M.
A. H. Robins Company
1405 Cummings Drive
P.O. Box 26609
Richmond, VA 23261-6609

Subject: Product Name: VirKon S
EPA Registration No.: 778-91
Your Amendment Dated January 5, 1990

Dear Dr. Miller:

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is not acceptable, for the reason given below.

For the perfume [REDACTED] ask your supplier to submit to the Agency (a) a Material Safety Data Sheet, which should include Health Effects; and (b) chemical composition, which should include, for each chemical in the perfume mixture, the chemical name, the CAS Registry number, and the percentage or percentage range of the chemical in the perfume mixture.

Your Confirmatory Efficacy data and Confidential Statement of Formula are acceptable.

If you have any questions, you may call Wallace Powell at (703) 557-6938.

Sincerely,

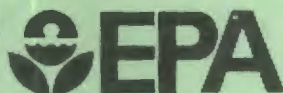
WCF

Walter C. Francis
Acting Product Manager (PM-32)
Antimicrobial Program Branch
Registration Division (H-7504C)

CONCURRENCES

SYMBOL							
SURNAME							
DATE							

A.S.


 United States Environmental Protection Agency
 Office of Pesticide Programs
 Washington, DC 20460

Data Review Record

 Confidential Business Information - Does not contain
 National Security Information (E.O. 12065)

Pack Number

Date Received

1. Product Name

Chemical Name

Kirkon S

Potassium Monopersulfate

2. Identifying Number	3. Record Number	4. Action Code	5. MRID/ Accession Number	6. Study Guideline or Narrative
778-91	259814	345	413821-1	Product Chemistry

7. Reference No.	8. Date Rec'd (EPA)	9. Prod/Review Mgr/DCI	10. PM/RM Team No.	11. Date to HED/ EFED/RD/BEAD	12. Proj Return Date	13. Date Returned to RD/SRRD
4	1-12-90	Francis	32	2-21-90	4-4-90	

Instructions

please review for addition of coloring agent

Split review

This Section Applies to Review of Studies Only

14. Check Applicable Box

<input type="checkbox"/> Adverse 6(a)(2) Data (405)	<input type="checkbox"/> Generic Data (Reregistration)(660)
<input type="checkbox"/> Special Review Data (870)	<input type="checkbox"/> Product Specific Data (Reregistration)(655)

15. No. of Individual Studies Submitted

16. Have any of the above studies (in whole or in part) been previously submitted for review?

<input type="checkbox"/> Yes (Please identify the study(ies))	<input type="checkbox"/> No
---	-----------------------------

17. Related Actions

18.	To	Type of Review	19. Reviews Also Sent to	20. Data Review Criteria
HED		Science Analysis & Coordination	<input type="checkbox"/> SAC <input type="checkbox"/> PC	A. Policy Note No. 31 <input type="checkbox"/> 1 = data which meet 6(a)(2) or meet 3(c)(2)(B) flagging criteria <input type="checkbox"/> 2 = data of particular concern from registration standard <input type="checkbox"/> 3 = data necessary to determine tiered testing requirements
		Toxicology/HFA	<input type="checkbox"/> TOX/HFA <input type="checkbox"/> PL	
		Toxicology/IR	<input type="checkbox"/> TOX/IR	
		Dietary Exposure	<input type="checkbox"/> DEB <input type="checkbox"/> EA	
		Nondietary Exposure	<input type="checkbox"/> NDE <input type="checkbox"/> AC	
EFED		Ecological Effects	<input type="checkbox"/> EEB <input type="checkbox"/> BA	B. Section 18 <input type="checkbox"/> 1 = data in support of section 3 in lieu of section 18
		Environmental Fate & Groundwater	<input type="checkbox"/> EFGWB	
SRRD		Special Review	<input type="checkbox"/> SR	C. Inert Ingredients <input type="checkbox"/> 1 = data in support of continued use of List 1 inert
		Reregistration	<input type="checkbox"/> RER	
		Generic Chemical Support	<input type="checkbox"/> GSC	
RD		Insecticide-Rodenticide	<input type="checkbox"/> IR	
		Fungicide-Herbicide	<input type="checkbox"/> FH	
		Antimicrobial	<input type="checkbox"/> AM	
		Product Chemistry		
BEAD		Precautionary Labeling		
		Economic Analysis		
		Analytical Chemistry		
		Biological Analysis		

☐ Confidential Statement of Formula (EPA Form 8570-4) Attached (Trade Secrets)

☒ Label Attached

Product Chemistry Review
RSB

EPA Reg. No. or File Symbol 778-91
Data Division Received 1-12-90
Products Manager No. 32 (Francis)
Product Name Virkon S
Company Name A. H. Robins Company, Inc.

100.0 Comments:

a. Addition of dye, [REDACTED] and perfume, [REDACTED] to this formulation would be acceptable.

b. However for [REDACTED] perfume ask your supplier to submit to this Agency complete chemical composition and Material Safety Data Sheet and Health Effects. For each component in perfume mixture include chemical name, CAS Registry number and percentage or range in the percentage of each component in the perfume mixture.

Anna Skapars
2-23-90

Inert ingredient information may be entitled to confidential treatment



United States Environmental Protection Agency
Office of Pesticide Programs
Washington, DC 20460

Data Review Record

Confidential Business Information - Does not contain
National Security Information (E.O. 12065)

Pack Number

Date Received

1. Product Name

Virkon S

Chemical Name

Potassium Monopersulfate

2. Identifying Number	3. Record Number	4. Action Code	5. MRID/ Accession Number	6. Study Guideline or Narrative
778-91	259814	245	413821-1	Efficacy

7. Reference No.	8. Date Rec'd (EPA)	9. Prod/Review Mgr/DCI	10. PM/RM Team No.	11. Date to HED/ EFED/RD/BEAD	12. Proj Return Date	13. Date Returned to RD/RRRD
4	1-12-90	Francis	32	2-21-90	4-4-90	2/28/90

Instructions

please review for addition of coloring agent

split review

This Section Applies to Review of Studies Only

14. Check Applicable Box	15. No. of Individual Studies Submitted
<input type="checkbox"/> Adverse 6(a)(2) Data (405) <input type="checkbox"/> Special Review Data (870)	
<input type="checkbox"/> Generic Data (Reregistration) (660) <input type="checkbox"/> Product Specific Data (Reregistration) (655)	
16. Have any of the above studies (in whole or in part) been previously submitted for review?	17. Related Actions
<input type="checkbox"/> Yes (Please identify the study(ies)) <input type="checkbox"/> No	

18.	To	Type of Review	19. Reviews Also Sent to	20. Data Review Criteria
HED		Science Analysis & Coordination	<input type="checkbox"/> SAC <input type="checkbox"/> PC	A. Policy Note No. 31
		Toxicology/HFA	<input type="checkbox"/> TOX/HFA <input type="checkbox"/> PL	
		Toxicology/IR	<input type="checkbox"/> TOX/IR	
		Dietary Exposure	<input type="checkbox"/> DEB <input type="checkbox"/> EA	<input type="checkbox"/> 1 = data which meet 6(a)(2) or meet 3(c)(2)(B) flagging criteria
		Nondietary Exposure	<input type="checkbox"/> NDE <input type="checkbox"/> AC	<input type="checkbox"/> 2 = data of particular concern from registration standard
EFED		Ecological Effects	<input type="checkbox"/> EEB <input type="checkbox"/> BA	
		Environmental Fate & Groundwater	<input type="checkbox"/> EFGWB	
SARD		Special Review	<input type="checkbox"/> SR	<input type="checkbox"/> 3 = data necessary to determine tiered testing requirements
		Reregistration	<input type="checkbox"/> RER	
		Generic Chemical Support	<input type="checkbox"/> GSC	
RD		Insecticide-Rodenticide	<input type="checkbox"/> IR	B. Section 18
		Fungicide-Herbicide	<input type="checkbox"/> FH	
		Antimicrobial	<input type="checkbox"/> AM	<input type="checkbox"/> 1 = data in support of section 3 in lieu of section 18
		Product Chemistry		
BEAD		Precautionary Labeling		C. Inert Ingredients
		Economic Analysis		
		Analytical Chemistry		
		Biological Analysis		<input type="checkbox"/> 1 = data in support of continued use of List 1 inert

☒ Confidential Statement of Formula
(EPA Form 8570-4) Attached (Trade Secrets)

☒ Label Attached

CONFIRMATORY DATA

EFFICACY EVALUTION AND TECHNICAL MANAGEMENT SECTION

Antimicrobial Program Branch

In 01-12-90 Out 02-27-90

EPA Reg. No. or File Symbol 778-91

Product Name VIRKON-S

Company Name A. H. Robins Company, Inc.

Submission Purpose Confirmatory Data for change in coloring agent

Date Application Received 02-21-90

Active Ingredients g

Potassium peroxymonosulfate 20.4g

Sodium Chloride 1.5g

Data Accession No. or Identification No. 413821-01 Product Manager No. 31

Recommendations:

Confirmatory data were submitted to support efficacy claims indicated on the specimen prototype label () the subject product as:

 hospital disinfectant

 X general disinfectant

 sanitizer for food contact surfaces

(1) The data are acceptable X

(2) The data are not acceptable See explanation below.

Labeling

a. No adverse comments.

Reviewed by Emily H. Mitchell
Emily H. Mitchell

WEC
2/28/90

Date 02-27-90

02/13/90

Product Name: VIRKON S
Company Name: A.H. ROBINS COMPANY
Application No.: 128563
EPA Reg. No.: 778-91
EPA Receipt Date: 01/12/90

Subject: Front End Screen for an Amendment

Dear Sir or Madam:

Your application for registration has been received by the Office of Pesticide Programs and has passed a preliminary screen for completeness. It will be placed in line for review to determine its acceptability. The application will be processed in chronological order of receipt.

Although the 1988 FIFRA amendments mandate EPA to review applications for expedited registration or amendments within 90 days, this turnaround time will not be met immediately due to the backlog of applications received before December 24, 1988. However, EPA is increasing human and automated resources and making necessary procedural changes in order to eliminate the backlog and to meet the 90-day response time as soon as possible.

If you have any questions, you may contact Jeff Kempter, Product Manager 32 at (703)-557-3964.

Sincerely,

Edith M. Menez
Team Leader
Front End Processing Staff
Registration Support Branch
Registration Division (H7504C)

H7504C
F Menez
2-13-90

A-H-ROBINS

Robert L. Miller, D.V.M.
Vice President, Office of Veterinary Medicine

A. H. Robins Company
1405 Cummings Drive
P. O. Box 26609
Richmond, Virginia 23261-6609
Cable Robinco /TWX 7109560001
Telephone (804) ~~257-2879~~ 257-2879

Mr. Jeff Kempter
Product Manager (32)
Antimicrobial Products Branch
Registration Division (H7505C)
U.S. Environmental Protection Agency
1921 Jefferson Davis Highway
Arlington, VA 22202

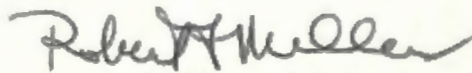
January 5, 1990

Re: VirKon S, 778-91

Dear Mr. Kempter:

We wish to amend the original registration to provide for an alternate formulation containing a coloring agent.

Sincerely,


R. L. Miller, D.V.M.

dhc

Enclosures

953



United States Environmental Protection Agency
Office of Pesticide Programs (TS-767)
Washington, DC 20460

OPP Identifier Number

128563

Application for Pesticide: ☐ Registration
☒ Amendment

Section I

1. Company/Product Number 778-91 2. Date 1/5/90 3. Product Manager Jeff Kempter (32) 4. Proposed Classification ☒ General ☐ Restricted

5. Name and Address of Applicant (Include ZIP Code)

A. H. Robins Company
1405 Cummings Drive
P. O. Box 26609
Richmond, VA 23261-6609

☐ Check if this is a new address

6. Product Name

VirKon S

Section II - Amendment Information

1. Subject

☐ Resubmission in response to Agency letter ☐ Final printed label in response to Agency letter ☒ Other (explain below)

Date of Letter

Amending original application for addition of coloring agent.

Section III

1. Material This Product Will Be Packaged In
Child-Resistant Packaging ☒ Yes ☐ No
Unit Packaging ☐ Yes ☒ No
If "Yes," Unit package wgt No. per container
Water-Soluble Packaging ☐ Yes ☒ No
If "Yes," Package weight No. per container
2. Type of Container ☒ Metal ☐ Plastic ☐ Glass ☐ Paper ☐ Other (Specify)
3. Location of Net Contents Information ☒ Label ☐ Container
4. Size(s) of Retail Container 5 kg
5. Location of Label Directions ☒ On Label ☐ On material accompanying product
6. Manner in Which Label Is Affixed To Product ☐ Lithograph ☒ Paper glued ☐ Other (Specify) ☐ Stenciled

Section IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application).

Name

Robert L. Miller, D.V.M.

Title

Vice President, Office of Veterinary Medicine

Telephone No. (Include Area Code)

(804) 257-2879

6. Date Application Received (Stamped)

Certification
I certify that the statements I have made on this form and all attachments thereto are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

2. Signature

3. Title

Vice President, Office of Veterinary Medicine

4. Typed Name

Robert L. Miller, D.V.M.

5. Date Signed

January 5, 1990

Paperwork Reduction Act Notice and Instructions

Paperwork Reduction Act Notice

Public reporting burden for this collection of information is estimated to average of 0.85 hours per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503.

Instructions

General

This form is to be used for all applications for new and amended registrations for pesticide products.

In order to process an application for new registration submitted on this form, the following material must accompany the application:

1. Offer to Pay Statement (EPA Form 8570-22, -23, or -24). (If not exempted by 40 CFR 162.9-1(b).)
2. Confidential Statement of Formula (EPA Form 8570-4).
3. Five copies of draft labeling.
4. Three copies of any data submitted.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8 1/2 x 11 inch paper or as a mockup of the proposed label. If prepared as a mockup it should be constructed in such a way as to facilitate storage in an 8 1/2 x 11 inch file. Mockup labels significantly smaller than 8 1/2 x 11 inches should be mounted on 8 1/2 x 11 inch paper for submission.

Submission of Data - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

Specific

Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Section I, III, and IV must be completed by the applicant. For applications submitted in connection with amended registration actions, Section I, II, and IV must be completed by the applicant.

Block A - Check the appropriate action for which you are submitting this form.

Section I - This Section must be completed for both Registration and Amended Registration actions.

1. **Company/Product Number** - Insert your company number, if one has been assigned. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If application is for an amendment, insert the registration number of the product.
2. **Date** - Fill in the appropriate date.
3. **Product Manager** - If known, fill in the name and number of the Product Manager.
4. **Proposed Classification** - Specify the proposed classification for this product.
5. **Name and Address of Applicant** - The name of the firm or person and address shown in your application is the person or firm to whom registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters.

An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.

6. **Product Name** - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.

Amendment Information

Section II - This Section must be completed for all applications submitted in connection with Amended Registration.

1. **Subject of Amendment** - Check the appropriate block, and provide a brief explanation of the purpose(s) for the amendment, such as: "the addition of a site, pest, or crop"; "to change inert ingredient"; "general label revisions of precautionary statements," etc.

Packaging and Container Information

Section III - This Section must be completed for all applications submitted in connection with New Registration.

1. **Type of Packaging** - Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
2. **Type of Retail Container** - Indicate type of container in which product will be marketed.
3. **Location of Net Contents** - Specify the net contents of all retail containers for your product.
4. **Size(s) of Retail Container** - Specify the net contents of all retail containers for your product.
5. **Location of Use Directions** - Indicate the location of the use directions for your product.
6. **Manner in which label is affixed to product** - Indicate the method product labeling is attached to retail container.

Contact Point

Section IV - This Section must be completed for all Registration and Amended Registration applications.

- 1-5. Self-explanatory.
6. EPA Use Only.

TRANSMITTAL DOCUMENT

Submitted

A. H. Robins Company
1405 Cummings Drive
P. O. Box 26609
Richmond, VA 23261-6609

Transmittal Date

January 5, 1990

Regulatory Action Supporting

Amendment, Addition of Coloring Agent
EPA Reg. No. 778-91
Submitting in support of application

List of Submitted Studies

Prince, Daniel L., Ph.D. (1989), Lot Nos. 89/11/01, 89/11/02, EPA Amended
Registration of VirKon-S Disinfectant AOAC Use Dilution Test, unpublished
report prepared by Gibraltar Laboratories, Inc., Fairfield, NJ, 13 pp.

MRID # _____

End of List

Transmitting Official

Robert L. Miller, D.V.M.
Vice President, Office of Veterinary Medicine
A. H. Robins Company

Robert L. Miller
(Signature)

(804) 257-2879

(Phone)

Robert L. Miller, D.V.M.
Vice President, Office of Veterinary Medicine

A. H. Robins Company
1405 Cummings Drive
P. O. Box 26609
Richmond, Virginia 23261-6609
Cable Robinco /TWX 7109560001
Telephone (804) ~~257-2879~~ 257-2879

A-H-ROBINS

Mr. Jeff Kempter
Product Manager (32)
Antimicrobial Products Branch
Registration Division (H7505C)
U.S. Environmental Protection Agency
1921 Jefferson Davis Highway
Arlington, VA 22202

November 29, 1989

Re: VirKon S
EPA File Symbol 778-OR

Dear Mr. Kempter:

This letter will summarize our telephone conversation regarding requirements for adding a coloring agent and fragrance to VirKon S.

We will conduct antibacterial testing on two separate lots against Staphylococcus aureus and Salmonella choleraesuis. We will submit as an alternate formulation and include a revised Confidential Statement of Formula and refer to the original submission.

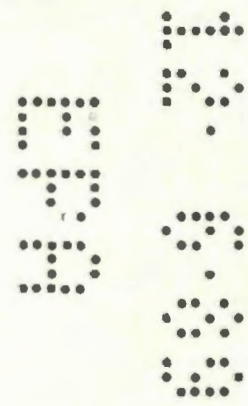
Sincerely,

R L Miller

R. L. Miller, D.V.M.

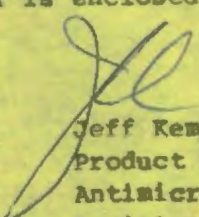
dhc

c: Mr. D. L. Gilbert
Dr. J. D. Wilson



If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIPRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the label is enclosed for your records.



Jeff Kempter
Product Manager (32)
Antimicrobial Program Branch
Registration Division (H7505C)

Enclosures

FRONT PANEL

VIRKON S
Broad Spectrum Disinfectant

For Use in Cleaning and Disinfecting Industrial
Animal and Agricultural Facilities

EFFECTIVE AGAINST--

BACTERIA:

Streptococcus pyogenes
Campylobacter pyloridas
Klebsiella pneumoniae
Escherichia coli
Salmonella typhimurium
Salmonella choleraesuis
Pseudomonas aeruginosa
Staphylococcus aureus
Staphylococcus epidermidis
Mycoplasma gallisepticum

VIRUSES OF:

Newcastle Disease
Infectious Bronchitis
Infectious Bursal Disease
Avian Laryngotracheitis
Avian Influenza
Marek's Disease

FUNGI:

Aspergillus flavus
Aspergillus fumigatus
Candida Albican

ACCEPTED
with COMMENTS
in EPA Letter Dated:

DEC 8 1989

Under the Federal Insecticide,
Fungicide, and Rodenticide Act
as amended, for the pesticide
registered under EPA Reg. No.

Active Ingredients

Potassium peroxymonosulfate.....778-91 20.47

Sodium Chloride..... 1.5%

Inert Ingredients..... 78.1%
100.0%

Equivalent to 9.75% Available Chlorine

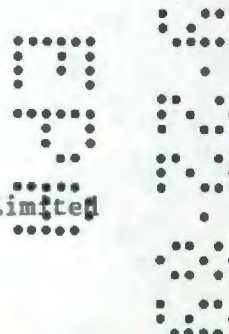
KEEP OUT OF REACH OF CHILDREN

DANGER:

See Back Panel for Additional Precautions

Net Weight 11 lbs (5.0 kg)

VIRKON S is a registered trademark of Antec International Limited
U. S. Patent Pending



BACK PANEL

VIRKON S Broad Spectrum Disinfectant

VIRKON S is effective against numerous microorganisms affecting animals: viruses, gram positive and gram negative bacteria, fungi (molds and yeasts), and mycoplasma. Efficacy was determined in the presence of hard water and organic material.

Controls:

Viruses of - Newcastle Disease, Infectious Bronchitis, Infectious Bursal Disease, Laryngotracheitis, Avian Influenza, and Marek's Disease

Fungi (molds and yeasts) - Aspergillus flavus, Aspergillus fumigatus, and Candida Albicans

Bacteria - Streptococcus pyogenes, Campylobacter pyloridas, Klebsiella pneumoniae, Escherichia coli, Salmonella typhimurium, Salmonella choleraesuis, Pseudomonas aeruginosa, Staphylococcus aureus, Staphylococcus epidermidis, Mycoplasma gallisepticum

DIRECTIONS FOR USE

Federal law prohibits use of this product in a manner inconsistent with its labeling.

This powder formula is easily diluted for use in manual or machine operations.

VIRKON S is recommended for use in hatcheries, chicken houses, and processing plants.

HATCHERIES: VIRKON S at 1% is generally suitable for cleaning and disinfecting hatches, setters, evaporative coolers, humidifying systems, ceiling fans, chicken houses, transfer trucks, trays, and plastic chick boxes (use 2% for Mycoplasma, Aspergillus flavus, and Aspergillus fumigatus).

BROILER/BREEDER HOUSES: Following removal of chickens, feed, and water troughs, remove manure and litter and spray floors and side walls with VIRKON S at 1%. Thoroughly wash waterers and feeders with a 1% solution of VIRKON S (use 2% for Mycoplasma, Aspergillus flavus, and Aspergillus fumigatus). After contact for 10 minutes, rinse with potable water. Do not use to house poultry or employ equipment until treatment has dried.

PROCESSING PLANTS: For disinfecting and cleaning walls, ceilings, and floors spray at a dilution of 1%.

Quantity of Final Solution	DILUTION CHART	
	1%	2%
1 gallon	1.3 ounces	2.7 ounces
10 gallons	13.4 ounces	26.7 ounces
50 gallons	66.8 ounces	133.5 ounces

For DISINFECTING use a rate of 7.5 gallons/1000 sq. ft.

for CLEANING AND DISINFECTING use a rate of 15 gallons/1000 sq. ft.

BACK PANEL (continued)

Storage and Disposal - Store in a cool, dry place in tightly closed container. Always replace lid after use. Wash empty container thoroughly and dispose of in trash.

PRECAUTIONARY STATEMENTS

Hazards To Humans and Domestic Animals - Corrosive. Causes skin burns and irreversible eye damage. Harmful if swallowed, absorbed through skin, or inhaled. Do not get in eyes, on skin, or on clothing. Wear protecting clothing and rubber gloves. Avoid breathing dust. Wear goggles, face shield, or safety glasses. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

Practical Treatment

If in eyes: Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes. Get prompt medical attention.

If on skin: Wash with plenty of soap and water. Get medical attention if irritation persists.

If inhaled or symptoms of coughing, choking, or wheezing are troublesome, remove to fresh air and seek medical attention.

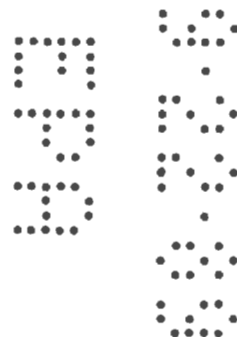
If swallowed: Drink promptly a large quantity of water. Avoid alcohol.

Notice to Physician: Probable mucosal damage may contraindicate the use of gastric lavage.

Manufactured for
Agri-Bio Corporation
966 Dorsey Street
Gainesville, Georgia 30501
U.S.A.

EPA Reg. No. 778-_____

EPA Est. No.



EFFICACY EVALUATION AND TECHNICAL MANAGEMENT SECTION
EFFICACY REVIEW - I

Antimicrobial Program Branch

IN 10-10-89

OUT 10-27-89

Reviewed By Emily H. Mitchell

11/2/89 Date 10-27-89

EPA Reg. No. or File Symbol 778-OR

EPA Petition or EUP No. None

Date Division Received 10-23-89

Type Product(s) General Disinfectant

Data Accession No.(s) HRID 412-59701

Product Mgr. No. PM 32 (Kempter)

Product Name(s) VIRKON-S

Company Name(s) A. H. Robins Company, Inc.

Submission Purpose Resubmission with additional data/information &
proposed label

Chemical & Formulation Powder

Active Ingredient(s):

Potassium peroxymonosulfate	20.4%
Sodium Chloride	1.5%

EFFICACY EVALUATION AND TECHNICAL MANAGEMENT SECTION
EFFICACY REVIEW - II

Antimicrobial Program Branch

EPA Reg. No. or File Symbol 778-OR
Date Division Received 10-23-89
Data Accession No.(s) _____
Product Manager No. PM 32 (Kempter)
Product Name VIRKON-S
Company Name A. H. Robins Company, Inc.

202.0 Recommendations

202.1 Efficacy Supported by the Data:

The data/information submitted clarifies the previous report.

203.0 Labeling

No adverse comments.

U. S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs

OCT 18 1989

A.H. ROBINS CO. INC.
P. O. BOX 26609
1405 CUMMINGS DR.
RICHMOND, VA 23261

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your transmittal of 10/10/89. Our staff has completed a preliminary analysis of the material. The results are provided as follows.

Your submittal was found to be substantially in compliance with the standards for submission of data contained in PR Notice 86-5, with the exception(s) noted below. A copy of your bibliography is enclosed, annotated with the Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents, and correct the noted exception(s) in future data submittals. If deficiencies were found which apply to your overall submission, they are described following this paragraph. If the deficiencies apply to specific studies, they are listed below following the applicable identification number or MRID. Thank you for your cooperation.

Any document which has been assigned a MRID has been accepted under PR Notice 86-5. If any comments related to a MRID appear on this report, they are provided for your information and reference when preparing future submissions.

If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

MRID 41259701

Studies must be continuously paginated from the title page through the end of the study and all appendices--except for the Confidential Attachment or Supplemental Statement of Confidentiality Claims, if present--even when the study is large enough to span more than one physical volume.

Each of the independent study reports in this group should have been bound as a separate study.

Data Requirement Listings, Data Call-In Coversheets, EPA form 8570-1, EPA form 8570-4 and labels are considered to be administrative material rather than data and should not be bound as part of a study.

412597-~~00~~

Robert L. Miller, D.V.M.
Vice President, Office of Veterinary Medicine

A. H. Robins Company
1405 Cummings Drive
P. O. Box 26609
Richmond, Virginia 23261-6609
Cable Robenco / TWX 7109560811
Telephone (804) ~~XXXXXX~~ 257-2879

A-H-ROBINS

Mr. Jeff Kempter
Product Manager (32)
Antimicrobial Products Branch
Registration Division (H7505C)
U.S. Environmental Protection Agency
1921 Jefferson Davis Highway
Arlington, VA 22202

October 5, 1989

Re: VirKon S
EPA File Symbol 778-OR

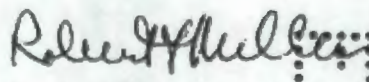
Dear Mr. Kempter:

Reference is made to your letter of September 28, 1989, regarding our supplemental submission of September 22, 1989.

The document rejected because of no title page or Statement of Data Confidentiality was not a report intended to stand on its own. It was an amendment to report number 48881, a part of the original submission. We are resubmitting the report containing the amendment. Since the original report contains a title page and Statement of Data Confidentiality, we believe we have satisfactorily responded to your questions. The report is presented in Attachment I (three copies).

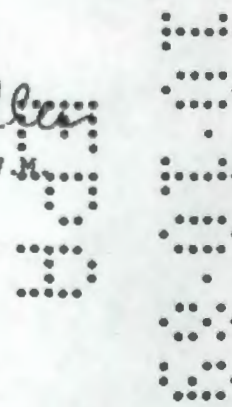
Attachment II (five copies) is revised labeling that complies with your letter of August 28, 1989.

Sincerely,


R. L. Miller, D.V.M.

dhc

Enclosures



ATTACHMENT I

236

TRANSMITTAL DOCUMENT

Submitter

A. H. Robins Company
1405 Cummings Drive
P. O. Box 26609
Richmond, VA 23261-6609

Transmittal Date

October 5, 1989

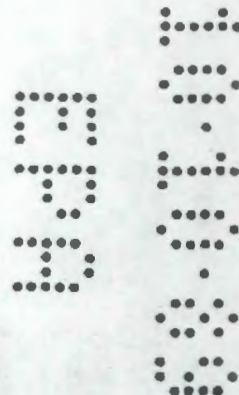
Regulatory Action Supporting

Registration, VirKon S
EPA Reg. No. 778-OR

List of Submitted Studies

1. Prince, Daniel L., Ph.D. - (1989) EPA Primary Registration of VirKon S Disinfectant, AOAC Use Dilution Test, unpublished report prepared by Gibraltar Biological Laboratories, Inc., Fairfield, NJ, 18 pp.

MRID # 41259701



file

778-OR

U. S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs

SEP 28 1989

A.H. ROBINS CO. INC.
P. O. BOX 26609
1405 CUMMINGS DR.
RICHMOND, VA 23261

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your transmittal of 09/22/89. Our staff has completed a preliminary analysis of the material. The results are provided as follows.

We are unable to accept your data submittal for further processing and review, because of the significant deficiencies noted below. It is being returned to you for correction. If deficiencies were found which apply to your overall submission, they are described immediately following this paragraph. If problems are found with individual studies, they are described below linked to the study identifier found on the enclosed copy of your bibliography.

The rejected documents below are identified with numbers which correlate to those taken from your submitted bibliography.

(01)

You must include one of the two acceptable statements of data confidentiality claims under FIFRA section 10(d)(1)(A), (B), or (C) as the second element in each study. The language of two alternative forms of the Statement of Data Confidentiality Claims, shown in Attachment 3 of PR Notice 86-5, cannot be altered. See pages 8 and 13 of the Notice.

- * No title page was included for this study.

CARLTON J. KEMPTER
PRODUCT MANAGER-32
DISINFECTANTS BRANCH

Robert L. Miller, D.V.M.
Vice President, Office of Veterinary Medicine

A. H. Robins Company
1405 Cummings Drive
P. O. Box 26609
Richmond, Virginia 23261-6609
Cable Robinco / TWX 7109560001
Telephone (804) ~~XXXXXX~~ 257-2879

A-H-ROBINS

Mr. Jeff Kempter
Product Manager (32)
Antimicrobial Products Branch
Registration Division (H7505C)
U.S. Environmental Protection Agency
1921 Jefferson Davis Highway
Arlington, VA 22202

September 18, 1989

Re: VirKon S
EPA File Symbol 778-OR

Dear Mr. Kempter:

I refer to your letter of August 28, 1989, regarding our application for registration of VirKon S.

The enclosed revised labeling (Attachment I, five copies) addresses the deficiencies discussed in your letter. Attachment II (three copies) provides phenol resistance data.

I believe this submission addresses all deficiencies in the original application.

Sincerely,

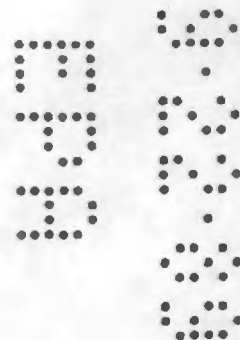
Robert L. Miller

R. L. Miller, D.V.M.

dhc

Enclosures

c: Dr. H. L. Easterbrooks
Mr. D. L. Gilbert
Mr. D. E. Jones
Mr. R. M. O'Hanlon
Dr. J. D. Wilson
Mr. Ralph Auchincloss (Antec)



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

AUG 28 1989

A.H. Robbins Company, Inc.
1405 Cummings Drive
P.O. Box 26609
Richmond, VA 23261-6609

Attention: H. Wayne Moran

Gentlemen:

Subject: VirKon S
EPA File Symbol 778-OK
Your Application Dated March 25, 1989

A review of your application for registration shows the following deficiencies.

Chemistry

According to your Confidential Statement of Formula (CSF) you may declare 20.4% Potassium peroxymonosulfate. Note that for the active ingredient the lower certified limit must be declared on the label.

If you intend to declare 22.5% Potassium peroxymonosulfate then submit revised CSF and revise certified limits for this ingredient.

Note the preferred declaration is: Potassium peroxymonosulfate.

Delete word Oxidant in front of Equivalent to 9.75% Available chlorine.

The net contents must be stated in terms of U.S. measure. There would then be no objection to an additional statement in terms of metric measure. It should be, Net Weight 110 lbs (50 kg). Enclosed product chemistry data is in compliance with 40 CFR Part 158.155 through 158.190 and is acceptable.

The accelerated storage and stability data at 37 °C for 25 days and for 6 months is acceptable on an interim basis. The results of 12 month stability test must be received by the Agency within 15 months after the granting of registration.

56958:I:Pringle:C.Disk:KENCO:K-4:08/24/89:10/06/89:de:JH:aw

CONCURRENCES

SYMBOL							
SURNAME							
DATE							

Efficacy

1. Efficacy Supported by the Data:

- a. The submitted data are acceptable to support effectiveness of the product, as a general disinfectant against all tested bacteria at a 1:100 dilution (1% in 400 ppm hard water) on hard non-porous surfaces for a contact time of 10 minutes. However, the phenol resistance must be provided for the tested bacteria. Refer to 2 below.
- b. The submitted virucidal data are acceptable to support effectiveness of the product against Newcastle Disease Virus at a 1:100 dilution on hard, non-porous surfaces for a contact time of 10 minutes.

2. Additional Data/Information Required to Support Efficacy:

- a. The phenol resistance must be provided for ~~all~~ ^{the required} tested bacteria.

WEC
9/7/89

0. Labeling

- a. On BACK PANEL change "Merek's Disease" to read "Marek's Disease".
- b. On BACK PANEL change "Sallmonella choleraesuis" to read "Salmonella choleraesuis".

Acute Toxicity

RECOMMENDATIONS

The data submitted are adequate to place the product tested in the following toxicity category:

	<u>STUDY</u>	<u>TOX CATEGORY</u>
Sensitization-Negative	Acute Oral	111 _____
	Acute Dermal	111 _____
	Acute Inhalation	111 _____
	Skin Irritation	1 <u>undiluted - IV - 5% dilution</u>
	Eye Irritation	1 <u>undiluted IV 5% dilution</u>

CRP STATUS

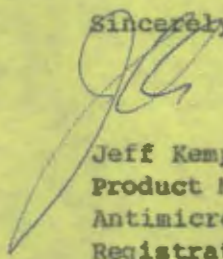
This product does not require special packaging. Expand Hazard to Human and domestic Animals to read: Corrosive. Causes skin "burns" and irreversible eye damage.

The Statement of practical treatment has to be revised to read "Get prompt medical attention" after the recommended eye treatment.

Delete the words "milk, egg white, gelatin solution, or if these are not available," . . .

If you have any further questions please contact Ms. Barbara Pringle at 703-557-0484.

Sincerely yours,



Jeff Kempter
Product Manager (32)
Antimicrobial Program Branch
Registration Division (H7505C)

FRONT PANEL

VIRKON-S
Broad Spectrum Disinfectant

For Use in Cleaning and Disinfecting Industrial
Animal and Agricultural Facilities

EFFECTIVE AGAINST--

BACTERIA:

Streptococcus pyogenes
Campylobacter pyloridas
Klebsiella pneumoniae
Escherichia coli
Salmonella typhimurium
Salmonella choleraesuis
Pseudomonas aeruginosa
Staphylococcus aureus
Staphylococcus epidermidis
Mycoplasma gallisepticum

VIRUSES OF:

Newcastle Disease
Infectious Bronchitis
Infectious Bursal Disease
Avian Laryngotracheitis
Avian Influenza
Marek's Disease

FUNGI:

Aspergillus flavus
Aspergillus fumigatus
Candida Albican

Active Ingredients

Potassium monopersulfate.....	22.5%
Sodium Chloride.....	1.5%
Inert Ingredients.....	76.0%
	<hr/>
	100.0%

Oxidant Equilavent to 9.75% Available Chlorine

KEEP OUT OF REACH OF CHILDREN

DANGER:

See Back Panel for Addition Precautions

Net Weight 5 kg

Virkon is a registered trademark of Antec International Limited
U. S. Patent Pending.

BACK PANEL

VIRKON-S Broad Spectrum Disinfectant

VIRKON-S is effective against numerous microorganisms affecting animals: viruses, gram positive and gram negative bacteria, fungi (molds and yeasts), and mycoplasma. Efficacy was determined in the presence of hard water and organic material.

Controls:

Viruses of - Newcastle Disease, Infectious Bronchitis, Infectious Brusal Disease, Laryngotracheitis, Avian Influenza, and Merek's Disease

Fungi (molds and yeasts) - Aspergillus flavus, Aspergillus fumigatus, and Candida Albicans

Bacteria - Streptococcus pyogenes, Campylobacter pyloridas, Klebsiella pneumoniae, Escherichia coli, Salmonella typhimurium, Sallmonella choleraesuis, Pseudomonas aeruginosa, Staphylococcus aureus, Staphylococcus epidermidis, Mycoplasma gallisepticum

DIRECTIONS FOR USE

Federal law prohibits use of this product in a manner inconsistant with its labeling.

This powder formula is easily diluted for use in manual or machine operations.

VIRKON_S is recommended for use in hatcheries, chicken houses, and processing plants.

HATCHERIES: VIRKON_S at 1% is generally suitable for cleaning and disinfecting hatchers, setters, evaporative coolers, humidifying systems, ceiling fans, chicken houses, transfer trucks, trays, and plastic chick boxes (use 2% for Mycoplasma, Aspergillus flavus, and Aspergillus fumigatus).

BROILER/BREEDER HOUSES: Following removal of chickens, feed, and feed water troughs, remove manure and litter and spray floors and side walls with VIRKON_S at 1%. Thoroughly wash waterers and feeders with a 1% solution of VIRKON_S. (use 2% for Mycoplasma, Aspergillus flavus, and Aspergillus fumigatus). After contact for 10 minutes, rinse with potable water. Do not use to house poultry or employ equipment until treatment has dried.

PROCESSING PLANTS: For disinfecting and cleaning walls, ceilings, and floors spray at a dilution of 1%.

DILUTION CHART

Quantity of
Final Solution

1%

2%

1 gallon

1.3 ounces

2.7 ounces

10 gallons

13.4 ounces

26.7 ounces

50 gallons

66.8 ounces

133.5 ounces

For DISINFECTING use a rate of 7.5 gallons /1000 sq. ft.

For CLEANING AND DISINFECTING use a rate of 15 gallons /1000 sq. ft.

BACK PANEL (cont'd)

Storage and Disposal - Store in a cool, dry place in tightly closed container. Always replace lid after use. Wash empty container thoroughly and dispose of in trash.

PRECAUTIONARY STATEMENTS

Hazards To Humans and Domestic Animals - Corrosive. Causes burns and irreversible eye damage. Harmful if swallowed, absorbed through skin, or inhaled. Do not get in eyes, on skin, or on clothing. Wear protecting clothing and rubber gloves. Avoid breathing dust. Wear goggles, face shield, or safety glasses. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

Practical Treatment

If in eyes: Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes.

If on skin: Wash with plenty of soap and water. Get medical attention if irritation persists.

If inhaled or symptoms of coughing, choking, or wheezing are troublesome, remove to fresh air and seek medical attention.

If swallowed: Drink promptly a large quantity of milk, egg white, gelatin solution, or, if these are not available, large quantities of water. Avoid alcohol.

Note to Physician: Probable mucosal damage may contraindicate the use of gastric lavage.

Manufactured for
Agri-Bio Corporation
966 Dorsey Street
Gainesville, Georgia 30501
U.S.A.

EPA Reg. No. 778-____

EPA Est. No.

Product Chemistry Review
RSB

EPA Reg. No. or File Symbol 778-OR

Date Division Received 4-7-89

Products Manager No. 32 (Kempter)

Product Name VIRKON S

Company Name A. H. Robins Co., Inc.

100.0 Comments:

- a. According to your Confidential Statement of Formula you may declare 20.4% Potassium peroxymonosulfate. Note that for the active ingredient the lower certified limit must be declared on the label.
If you intend to declare 22.5% Potassium peroxymonosulfate then submit revised Confidential Statement of Formula and revise certified limits for this ingredient.
- b. Note the preferred declaration is: Potassium peroxymonosulfate.
- c. Delete word Oxidant in front of Equivalent to 9.75% Available Chlorine.
- d. The net contents must be stated in terms of U.S. measure. There would then be no objection to an additional statement in terms of metric measure. It should be, Net Weight 110 lbs (50 kg)
- e. Enclosed product chemistry data is in compliance with 40 CFR Part 158.155 through 158.190 and is acceptable.
- f. The accelerated storage and stability data at 37°C for 28 days and for 6 months is acceptable on an interim basis. The results of 12 month stability test must be received by the Agency within 15 months after the granting of registration.

Note to Efficacy:
Should Sodium chloride be declared as active ingredient?

Anna Skapars 5-9-89
JRS 5/19/89 246

Title

Product Chemistry Data for
VirKon-S and its Active Ingredients

Data Requirements

Guideline 158.120

Author

A. H. Robins Company

Study Completed On

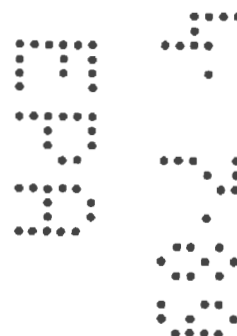
March 15, 1989

Performing Laboratory

A. H. Robins Company
1211 Sherwood Avenue
Richmond, VA 23261-6609

Laboratory Project

Product Data for VirKon-S



EFFICACY EVALUATION AND TECHNICAL MANAGEMENT SECTION
EFFICACY REVIEW - I

Antimicrobial Program Branch

IN 04-07-89

OUT 08-21-89

Reviewed By Emily H. Mitchell *WEC 8/21/89* Date 08-21-89

EPA Reg. No. or File Symbol 778-OR

EPA Petition or EUP No. None

Date Division Received 04-25-89

Type Product(s) General Disinfectant

Data Accession No.(s) 410574-10 & 410574-11 411083-01 & 411083-02

Product Mgr. No. PM 32 (Kempter)

Product Name(s) VIRKON-S

Company Name(s) A. H. Robins Company, Inc.

Submission Purpose New submission with efficacy data and proposed label

Chemical & Formulation Powder

Active Ingredient(s):

	<u>%</u>
Potassium monopersulfate	22.5%
Sodium Chloride	1.5%

200.0 Introduction

200.1 Uses:

A powder formula effective against numerous microorganisms affecting animals: viruses, gram positive and gram negative bacteria, fungi (molds and yeasts), and mycoplasma.

200.2 Background Information:

The submission received 04-25-89, is a new submission with efficacy data and proposed label provided.

201.0 Data Summary (Accession Nos. 410574-10 & 410574-11
411083-01 & 411083-02)

201.2 Brief Description of Tests:

- a. Reports of Bactericidal Tests by Daniel L. Prince, Ph.D.
Gibraltar Biological Laboratories, Inc.
122 Fairfield Road, Fairfield, New Jersey 07006
- b. Reports of Virucidal Tests by Daniel L. Prince, Ph.D.
Gibraltar Biological Laboratories, Inc.
122 Fairfield Road, Fairfield, New Jersey 07006

201.3 Test Summaries:

a. Bactericidal Tests

1. Method: A.O.A.C. Use Dilution Test, 14 Edition, 1984.
2. Modifications: 5% calf serum and 400 ppm A.O.A.C. hard water (CaCO₃)
3. Samples:

<u>Test Bacteria</u>	<u>Lot No.</u>	<u>Date Assayed</u>	<u>Date Completed</u>
P. <u>aeruginosa</u>	08109160	1-16-89-1-19-89	1-26-89
	02809160	1-23-89	
	03809160		
S. <u>aureus</u>	08109106	1-16-89-1-19-89	1-26-89
	02809160	1-23-89	
	03809160		
S. <u>choleraesuis</u>	01809106	1-16-89-1-19-89	1-26-89
	02809160	1-23-89	
	02809160		

E. <u>coli</u>	01809160 02809160	01-27-89	02-16-89
S. <u>pyogenes</u>	01809160 02809160	01-27-89	02-16-89
S. <u>typhi</u>	01809160 02809160	01-27-89	02-16-89
K. <u>pneumoniae</u>	01809160 02809160	01-27-89	02-16-89
S. <u>epidermidis</u>	01809160 02809160	01-27-89	02-16-89
C. <u>pyloridis</u>	01809160 02809160	01-27-89	02-16-89
C. <u>albicans</u>	01809160 02809160	01-27-89	02-16-89

4. Dilution: 1% in 400 ppm
5. Exposure: 10 minutes at 20-25°C
6. Subculture Medium/Neutralizer: Lethen Broth
7. Incubation of Subcultures: 48 hours at 35±1°C
8. Test Bacteria:

<u>Test Bacteria</u>	<u>Identification</u>	<u>Phenol Res.</u>
<u>Pseudomonas aeruginosa</u>	15442 ATCC	Not Listed
<u>Staphylococcus aureus</u>	6538 ATCC	Not Listed
<u>Salmonella choleraesuis</u>	10708 ATCC	Not Listed
<u>Streptococcus pyogenes</u>	GBL #7	Not Listed
<u>Salmonella typhi</u>	GBL #106	Not Listed
<u>Escherichia coli</u>	GBL #642	Not Listed
<u>Klebsiella pneumoniae</u>	GBL #132	Not Listed
<u>Staphylococcus epidermidis</u>	GBL #6	Not Listed
<u>Campylobacter pyloridis</u>	GBL #775	Not Listed
<u>Candida albicans</u>	GBL #648	Not Listed

9. Survival of Inoculum on Control Carriers:

<u>Test Bacteria</u>	<u>Average Colony Forming Units Per Carrier</u>		
<u>P. aeruginosa</u>	1.5 x 10 ⁶	1.8 x 10 ⁶	3.7 x 10 ⁵
<u>S. aureus</u>	7.2 x 10 ⁴	1.3 x 10 ⁶	1.6 x 10 ⁵
<u>S. choleraesuis</u>	1.6 x 10 ⁵	4.2 x 10 ⁵	1.6 x 10 ⁵
<u>S. pyogenes</u>		4.1 x 10 ⁴	
<u>S. typhi</u>		8.5 x 10 ⁵	
<u>E. coli</u>		1.7 x 10 ⁶	
<u>K. pneumoniae</u>		2.9 x 10 ⁶	
<u>S. epidermidis</u>		9.3 x 10 ⁴	
<u>C. pyloridis</u>		5.9 x 10 ⁵	
<u>C. albicans</u>		3.7 x 10 ⁴	

10. Test Results:

<u>Test Bacteria</u>	<u>Lot No.</u>	<u>No. Carriers Tested</u>	<u>No. of Carriers Demonstrating Growth</u>
<u>Pseudomonas aeruginosa</u>	01809160	60	0
	02809160	60	0
	03809160	60	0
<u>Staphylococcus aureus</u>	01809106	60	0
	02809160	60	0
	03809160	60	0
<u>Salmonella choleraesuis</u>	01809106	60	0
	02809160	60	0
	03809160	60	0
<u>Streptococcus pyogenes</u>	01809160	10	0
	02809160	10	0
<u>Salmonella typhi</u>	01809160	10	0
	02809160	10	0
<u>Escherichia coli</u>	01809160	10	0
	02809160	10	0

<u>Klebsiella</u>	01809160	10	0
<u>pneumoniae</u>	02809160	10	0
<u>Staphylococcus</u>	01809160	10	0
<u>epidermidis</u>	02809160	10	0
<u>Campylobacter</u>	01809160	10	0
<u>pyloridis</u>	02809160	10	0
<u>Candida</u>	01809160	10	0
<u>albicans</u>	02809160	10	0

11. Conclusions: Results show satisfactory performance of the product against all test bacteria when used at a 1% in 400 ppm dilution on hard non-porous surfaces for a contact time of 10 minutes. However, the phenol resistance must be provided for the bacteria tested.

c. Virucidal Tests

1. Method: EPA Test Method (DIS/TSS-7)
2. Modifications: 10% fetal calf serum and hard water
3. Samples:

<u>Batch No.</u>	<u>Preparation Date</u>	<u>Test Date</u>
45616/1D	04-05-89	04-11-89
45616/2D	04-05-89	04-11-89

4. Dilution: 1:100 (400 ppm A.O.A.C. H₂O) (1%)
5. Exposure: 20-25°C for 10 minutes
6. Recovery Medium/Neutralizer/Diluent: Trypticase Soy Broth with 10% calf serum
7. Incubation: 48 hours at 35°C
8. Test Virus Host System:

9-10 day old Chick Embryos

9. Drying Time and Temperature: 35°C for 30-45 minutes.
10. Assay System for Virus Recovery: Hemagglutination
11. Method For Estimating 50 per cent end point: Reed Muench Method
12. Test Virus: Newcastle Disease Virus
13. Test Results:

<u>ID-50 (-log 10)</u>					
<u>Test Virus</u>	<u>Batch No.</u>	<u>Virus Control</u>	<u>Virus Disin.</u>	<u>Toxicity Control</u>	<u>Virus Inactivation</u>
Newcastle Disease	45616/1D	4.4	1.0	1.0	3.4
	45616/2D	4.4	1.0	1.0	3.4

14. Conclusions: This product showed satisfactory performance against the test virus when used at a 1:100 dilution with 400 ppm A.O.A.C. water (1%) on hard, non-porous surfaces at a contact time of 10 minutes.

EFFICACY EVALUATION AND TECHNICAL MANAGEMENT SECTION
EFFICACY REVIEW - II

Antimicrobial Program Branch

EPA Reg. No. or File Symbol 778-OR
Date Division Received 04-25-89
Data Accession No.(s) 411083-01 & 411083-02 410574-10 & 410574-11
Product Manager No. PM 32 (Kempter)
Product Name VIRKON-S
Company Name A. H. Robins Company, Inc.

202.0 Recommendations

202.1 Efficacy Supported by the Data:

- a. The submitted data are acceptable to support effectiveness of the product, as a general disinfectant against all tested bacteria at a 1:100 dilution (1% in 400 ppm hard water) on hard non-porous surfaces for a contact time of 10 minutes. However, the phenol resistance must be provided for the tested bacteria. Refer to 202.2 below.
- b. The submitted virucidal data are acceptable to support effectiveness of the product against Newcastle Disease Virus at a 1:100 dilution on hard, non-porous surfaces for a contact time of 10 minutes.

202.2 Additional Data/Information Required to Support Efficacy:

- a. The phenol resistance must be provided for all tested bacteria.

203.0 Labeling

- a. On BACK PANEL change "Merek's Disease" to read "Marek's Disease".
- b. On BACK PANEL change "Sallmonella choleraesuis" to read "Salmonella choleraesuis".

TECHNICAL SUPPORT SECTION TOXICOLOGY REVIEW - I

Disinfectants Branch

May 19 89

May 19 89

IN

OUT

Reviewed by Alex Arce

Date May 19 89

EPA Reg. No. or File Symbol 778 OR

EPA Petition or EUP No. None

Date Division Received 4-25-89

Type Product(s): I, D, H, F, N, R, S

Data Accession No(s). 440574-02 to 09

Product Mgr. No. 32 Kempter

Product Name(s) VIRKON-S

Company Name(s) Agri-Bio Corporation

Submission Purpose Data label review - Registration

Chemical & Formulation liquid

Active Ingredient(s):

Potassium monopersulfate

22.5

Sodium Chloride

1.5

El Condor Form #1 3/88

BACKGROUND

The product will be used as a Disinfectant (Cleanin and Disinfecting
animal and Agricultural
facilities)

RECOMMENDATIONS

The data submitted are adequate to place the product tested in the following toxicity category:

	<u>STUDY</u>	<u>TOX CATEGORY</u>
Sensitization-Negative	Acute Oral	111_____
	Acute Dermal	111_____
	Acute Inhalation	111_____
	Skin Irritation	1 undiluted 1V 5% dilution
	Eye Irritation	1 undiluted 1V 5% dilution

CRP STATUS

m This product ~~does~~/does not require special packaging
Expand Hazard to Human and domestic Aimals to read: Corrosive. Causes skin"burns
and irreversible eye damage
The Statement of practical treatment has to be revised to read "Get prompt medical
attention " after the recommended eye treatment.
Delete the word " milk ".

DATA REVIEW

Test Laboratory: Biosearch Incorporated

88-6437A

Acute Oral LD₅₀ CFR 81.1

Report date: 01-24-89 MRID No. 410574-02

Method of Testing: CFR 81-1

Species: Rats

Sex: Male and Female

Levels Tested: 0.5, 1.00, 1.50, 1.78
2.00 and 2.50 g/kg

Age: Adults

No. Animals/dose: 5 m and 5 f

Weights: Acceptable

Via: Gavage

Material: Un diluted

Observation days: 14

Necropsy: all

Procedure

The rats were treated with the material by gavage and observed for signs of toxicity, changes in body weight and other meaningful parameters.

Results:

Signs of Toxicity: Lethargy, ruffled hair

Body Weights: Unremarkable

Mortality: -all at 2.00 and 2.50 g/kg, 2, at 1.78 (males) 4 at 1.50 and 2

Necropsy: Irritation of lungs and G. I tract at 1.00 g/kg

Conclusion: The Acute Oral LD₅₀ is 1.48 g/kg combined

Core Minimum data

Toxicity Category: III

Acute Dermal LD₅₀ CFR 81.2

Project 88-6437A

Report Date: 12-28-88

MRID No. 410574-03

Method of Testing: CFR 81-2

Species: rabbits

Levels Tested 2.0 g/kg

Sex: male and female

No./animals/dose 5m and 5 f

Age: Adults

Via: Occluded patch

Weight: Acceptable

Observation days: 14

Material: Undiluted

Necropsy: All

Procedure

The animals were treated with the amterial in previously clipped areas of the skin in the back , and observed for signs of toxicity and changes in body weights

Result

Signs of Toxicity: Dermal irritation

Mortality: none

Body weights: Unremarkable

Necropsy: Unremarkable

Conclusions: The Acute Dermal LD₅₀ is greater than 2.0 g/kg

Core Minimum data

Toxicity Category: III

Acute Inhalation LC₅₀

CFR 81.3

Report Date: 12-19-88

MRID: 410574-04

Method of Testing: CFR 81-3

Species: rabbits

Levels tested: 4.86 w/w

Sex: male and female

No. animals/dose: 5 and 5

Age: adults

Via: Inhalation chamber

Weight: Acceptable

Observation days: 14

Material: in deionized water

Necropsy: all

Procedure

The animals were exposed to the material in an inhalation 230 liter chamber for 242 minutes. Measurements of the concentration were monitored and the animals were observed for signs of toxicity and behavior.

Results

Signs of toxicity: Unremarkable

Mortality: None

Body Weights: Unremarkable

Necropsy: No gross pathology

Conclusions: The Acute Inhalation LC₅₀ is 6.147 mg/l combined

Core Minimum data

Toxicity Category: III

Primary Skin Irritation

CFR 81.5

2 test were performed . one using the undiluted material , the other a 5 % solution . This report is for the undiluted materia-
The procedures were similar

Report Date: 12 13 88

MRID No.: 410574-07 and -08

Method of Testing: CFR 81-5

Species: Rabbits

Observation days: 14 days

No. of animals 6

Material: Undiluted and 5 %

Dose: 0.5 ml

Via: Occluded patch

Areas: In the back

Necropsy: No

Procedure

The animals were treated with the material in previously
clipped areas of the back and observed for signs of toxicity

Results: Severe Irritation was found in 6/6 undiluted test animals

Conclusion: The product is a Severe skin irritant

The 5 % solution failed to induce irritation

Core Minimum data

Toxicity Category: 1

Primary Eye Irritation

CFR 81.4

This is a review of the undiluted material test. Other test using 5 % solution failed to induce irritation. Both test were performed following the same method

Report Date: 11-15-88

MRID No.: 410574-05 and 06

Method of Testing CFR 81-4

Species: Rabbits

Observation days: 2

Dose: 0.1 ml

Materials: Undiluted and 5 %

No. of animals: 6

Via: Eye instillation

Areas: In one eye

Necropsy: None

Procedure

The animals were treated with the material instilled in one eye , other served as control . Observation for ocular damage were followed

Results: 6/6 Corneal opacity 6/6 Iritis developed

Conjunctival irritation was severe

Eyes ~~not~~ cleared : Did not clear . test ended at day 2 due to corrosiveness

Core Minimum data

Toxicity Category: 1 - Corrosive

The 5 % dilution failed to induce severe or other damage

Dermal Sensitization

CFR. 81.6

Report Date: 01-26-89

MRID No. 41-05-74

Method of Testing: CFR 81-6

Specie: Guinea pigs

Observation days: after challenge

Dose: 0.5 ml

Challenge application day: 2 weeks after

Challenge dose: 0.5 ml

Via: occluded patch

Areas: In the back

No. of animals used: 9

Material: ~~5.5x 5 % w/w~~ solution in water

PROCEDURE The animals were treated with the material in previously clipped areas of the back for two weeks , after a rest period of two other weeks a challenge dose was applied . Observation for responses were performed .

Results:

Erythema : None

Edema: None

Conclusions: The product is not dermal sensitizer

Core Minimum data

Toxicity Category: N/a



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

Product Name: VIRKON-S
EPA File Symbol: 778-OR
Application Date: 3-25-89
Receipt Date: 4-7-89

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

APR 19 1989

Dear Registrant:

A cursory review of your application shows that it is incomplete. Please provide the item(s) below within 75 days or your application will be administratively withdrawn. Refer to the Code of Federal Regulations, Title 40, parts 152 to 180 for a full description of all requirements. If you have any questions, you may contact Brian Parry at 703-557-0484.

- ☐ Application (EPA form 8570-1 enclosed).
- ☐ Confidential Statement of Formula (EPA form 8570-4 enclosed).
- ☐ Formulator's Exemption (EPA form enclosed).
- ☐ Certification with Respect to Citation of Data (EPA form enclosed).
- ☐ Five copies of draft labeling.
- ☒ Three copies of data properly formatted per P.R. Notice 86-5:
 - ☐ Product chemistry (40 CFR 158.120).
 - ☐ Acute toxicity (40 CFR 158.135).
 - ☒ Efficacy (see enclosure).
- ☒ Other: See DIS-TDS enclosure and submit.
Confirmatory efficacy data. See enclosed label
with check in title. Human pathogens. When
confirmatory is submitted, all product chemistry
and confirmatory will
be reviewed at some
time.

Sincerely,

Jeff Kempter
Jeff Kempter
Product Manager 32
Antimicrobial Program Branch
Registration Division (TS-767C)

FRONT PANEL

VIRKON-S
Broad Spectrum Disinfectant

For Use in Cleaning and Disinfecting Industrial
Animal and Agricultural Facilities

EFFECTIVE AGAINST—

BACTERIA:

Streptococcus pyogenes
Campylobacter pyloridas
Klebsiella pneumoniae
Escherichia coli
Salmonella typhimurium
Salmonella choleraesuis
Pseudomonas aeruginosa
Staphylococcus aureus
Staphylococcus epidermidis
Mycoplasma gallisepticum

VIRUSES OF:

Newcastle Disease
Infectious Bronchitis
Infectious Bursal Disease
Avian Laryngotracheitis
Avian Influenza
Marek's Disease

FUNGI:

Aspergillus flavus
Aspergillus fumigatus
Candida Albican

Active Ingredients

Potassium monopersulfate.....	22.5%
Sodium Chloride.....	1.5%
Inert Ingredients.....	76.0%
	<hr/>
	100.0%

Oxidant Equilavent to 9.75% Available Chlorine

KEEP OUT OF REACH OF CHILDREN

DANGER:

See Back Panel for Addition Precautions

Net Weight 5 kg

Virkon is a registered trademark of Antec International Limited
U. S. Patent Pending.

BACK PANEL

VIRKON-S Broad Spectrum Disinfectant

VIRKON-S is effective against numerous microorganisms affecting animals: viruses, gram positive and gram negative bacteria, fungi (molds and yeasts), and mycoplasma. Efficacy was determined in the presence of hard water and organic material.

Controls:

Viruses of - Newcastle Disease, Infectious Bronchitis, Infectious Brusal Disease, Laryngotracheitis, Avian Influenza, and Merek's Disease

Fungi (molds and yeasts) - Aspergillus flavus, Aspergillus fumigatus, and Candida Albicans

Bacteria - Streptococcus pyogenes, Campylobacter pyloridas, Klebsiella pneumoniae, Escherichia coli, Salmonella typhimurium, Sallmonella choleraesuis, Pseudomonas aeruginosa, Staphylococcus aureus, Staphylococcus epidermidis, Mycoplasma gallisepticum

DIRECTIONS FOR USE

Federal law prohibits use of this product in a manner inconsistent with its labeling.

This powder formula is easily diluted for use in manual or machine operations.

VIRKON_S is recommended for use in hatcheries, chicken houses, and processing plants.

HATCHERIES: VIRKON_S at 1% is generally suitable for cleaning and disinfecting hatchers, setters, evaporative coolers, humidifying systems, ceiling fans, chicken houses, transfer trucks, trays, and plastic chick boxes (use 2% for Mycoplasma, Aspergillus flavus, and Aspergillus fumigatus).

BROILER/BREEDER HOUSES: Following removal of chickens, feed, and feed water troughs, remove manure and litter and spray floors and side walls with VIRKON_S at 1%. Thoroughly wash waterers and feeders with a 1% solution of VIRKON_S. (use 2% for Mycoplasma, Aspergillus flavus, and Aspergillus fumigatus). After contact for 10 minutes, rinse with potable water. Do not use to house poultry or employ equipment until treatment has dried.

PROCESSING PLANTS: For disinfecting and cleaning walls, ceilings, and floors spray at a dilution of 1%.

DILUTION CHART

Quantity of Final Solution	1%	2%
1 gallon	1.3 ounces	2.7 ounces
10 gallons	13.4 ounces	26.7 ounces
50 gallons	66.8 ounces	133.5 ounces

For DISINFECTING use a rate of 7.5 gallons /1000 sq. ft.

For CLEANING AND DISINFECTING use a rate of 15 gallons /1000 sq. ft.

BACK PANEL (cont'd)

Storage and Disposal - Store in a cool, dry place in tightly closed container. Always replace lid after use. Wash empty container thoroughly and dispose of in trash.

PRECAUTIONARY STATEMENTS

Hazards To Humans and Domestic Animals - Corrosive. Causes burns and irreversible eye damage. Harmful if swallowed, absorbed through skin, or inhaled. Do not get in eyes, on skin, or on clothing. Wear protecting clothing and rubber gloves. Avoid breathing dust. Wear goggles, face shield, or safety glasses. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

Practical Treatment

If in eyes: Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes.

If on skin: Wash with plenty of soap and water. Get medical attention if irritation persists.

If inhaled or symptoms of coughing, choking, or wheezing are troublesome, remove to fresh air and seek medical attention.

If swallowed: Drink promptly a large quantity of milk, egg white, gelatin solution, or, if these are not available, large quantities of water. Avoid alcohol.

Note to Physician: Probable mucosal damage may contraindicate the use of gastric lavage.

Manufactured for
Agri-Bio Corporation
966 Dorsey Street
Gainesville, Georgia 30501
U.S.A.

EPA Reg. No. 778-____

EPA Est. No.

U. S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs

A.H. ROBINS CO. INC.
P. O. BOX 28609
1405 CUMMINGS DR.
RICHMOND, VA 23261

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your transmittal of 04/07/89. Our staff has completed a preliminary analysis of the material. The results are provided as follows.

Your submittal was found to be substantially in compliance with the standards for submission of data contained in PR Notice 86-5, with the exception(s) noted below. A copy of your bibliography is enclosed, annotated with the Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents, and correct the noted exception(s) in future data submittals. If deficiencies were found which apply to your overall submission, they are described following this paragraph. If the deficiencies apply to specific studies, they are listed below following the applicable identification number or MRID. Thank you for your cooperation.

Any document which has been assigned a MRID has been accepted under PR Notice 86-5. If any comments related to a MRID appear on this report, they are provided for your information and reference when preparing future submissions.

If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

MRID 41057401

The Good Laboratory Practice Statement should appear on page 3 of the study. See page 17 of PR Notice 86-5.

The statement of data confidentiality claims must appear on page 2 of each study. See pages 6 and 17 of PR Notice 86-5.

A. H. Robins Company
 1407 Cummings Drive
 P. O. Box 26609
 Richmond, Virginia 23261-6609
 Cable Robinco/TWX 109560001
 Telephone (804) 252-2000

A-H-ROBINS

Mr. Jeff Kempler
 Product Manager (32)
 U.S. ENVIRONMENTAL PROTECTION
 AGENCY
 Insecticide-Rodenticide Branch
 1921 Jefferson Davis Hwy.
 Arlington, VA 22202

March 30, 1989

RE: Submission of Application for Registration of New Product
 VirKon-SR

Dear Mr. Edwards:

The A. H. Robins Company is submitting application for registration of the above named product. In accordance with applicable regulations, the following documentation is enclosed fulfilling the informational requirements for such registration.

- 1) EPA Form 8570-1; Application for Registration
- 2) Five (5) copies of proposed labeling
- 3) List of Registration Data Requirements
- 4) EPA Form 8570-28; Certification with Respect to Citation of Data
- 5) EPA Form 8570-4; Confidential Statement of Formula
- 6) Required Data: Product Chemistry, Acute Toxicology, Efficacy

Studies of the product's effectiveness against several of the claimed microbes have not been submitted. Submission was understood to be unnecessary as the agents were considered to not be human pathogens (statement enclosed).

For your information, we have also included a section from the manufacturers manual explaining the chemistry and possible method of action for the product.

Respectfully Submitted,

H. Wayne Moran
 H. Wayne Moran
 Manager, Regulatory Affairs
 Pet Care Products R&D
 Office of Veterinary Medicine

TRANSMITTAL DOCUMENT

Submitter

A. H. Robins Co.
1405 Cummings Drive
Richmond, VA 23261-6609

Transmittal Date

March 30, 1989

Regulatory Action Supporting

Registration, VirKon-S
EPA Reg. No. 778-OE

List of Submitted Studies

1. Product Chemistry Data for VirKon-S and its active ingredients. Unpublished report submitted by A. H. Robins Co., Richmond, VA

MRID# 41057401

2. Gabriel, David - (1988) A. H. Robins Disinfectant, Lot No. 02809160, Acute Oral Toxicity, LD50, AHR 88-197, unpublished report prepared by Biosearch, Inc., Philadelphia, PA, 19 pp.

MRID# 41057402

3. Gabriel, David - (1988) A. H. Robins Disinfectant, Lot No. 02809160, Acute Dermal Toxicity, LD50, AHR 88-199, unpublished report prepared by Biosearch, Inc., Philadelphia, PA, 8 pp.

MRID# 41057403

4. Herselman, Richard J. - (1988) VirKon-S, A. H. Robins Disinfectant, Lot No. 02809160, Acute Inhalation Toxicity, Single Level, AHR 88-198, unpublished report by Biosearch, Philadelphia, PA, 21 pp.

MRID# 41057404

5. Moore, George E. (1988) VirKon-S, A. H. Robins Disinfectant (Supplied), Lot No. 02809160, Primary Eye Irritation, AHR 88-195, unpublished report by Biosearch, Inc., Philadelphia, PA, 11 pp.

MRID# 41057405

TRANSMITTAL DOCUMENT (cont'd)

6. Moore, George E. - (1989) VirKon-S, A. H. Robins Disinfectant (5% Dilution), Lot No. 02809160, Primary Eye Irritation, AHR 88-195, unpublished report by Biosearch, Inc., Philadelphia, PA, 11 pp.

MRID# 41057406

7. Gabriel, David - (1989) VirKon-S, A. H. Robins Disinfectant (Supplied), Lot No. 02809160, Primary Skin Irritation, AHR 88-194, unpublished report by Biosearch, Inc., Philadelphia, PA, 9 pp.

MRID# 41057407

8. Gabriel, David - (1989) VirKon-S, A. H. Robins Disinfectant (5% Dilution), Lot No. 02809160, Primary Skin Irritation, AHR 88-194, unpublished report by Biosearch, Inc., Philadelphia, PA, 8 pp.

MRID# 41057408

9. Daniels, Donna S. - (1989) VirKon-S, A. H. Robins Disinfectant, Lot No. 02809160, Guinea Pig Dermal Sensitization - Modified Buehler Method, AHR 88-196, unpublished report by Biosearch, Inc., Philadelphia, PA, 16 pp.

MRID# 41057409

10. Prince, Daniel L., Ph.D. - (1989) EPA Primary Registration of VirKon-S Disinfectant, AOAC Use Dilution Test, unpublished report prepared by Gibraltor Biological Laboratories, Inc., Fairfield, NJ, 18 pp.

MRID# 41057410

11. Prince, Daniel L., Ph.D. - (1989) EPA Primary Registration of VirKon-S Disinfectant, AOAC Use Dilution Test, unpublished report prepared by Gibraltor Biological Laboratories, Inc., Fairfield, NJ, 15 pp.

MRID# 41057411

End of List

TRANSMITTAL DOCUMENT (cont'd)

Transmittal Official

H. Wayne Moran
Manager, Regulatory Affairs, Pet Care Products R&D, Office of Veterinary Medicine,
A. H. Robins Co.

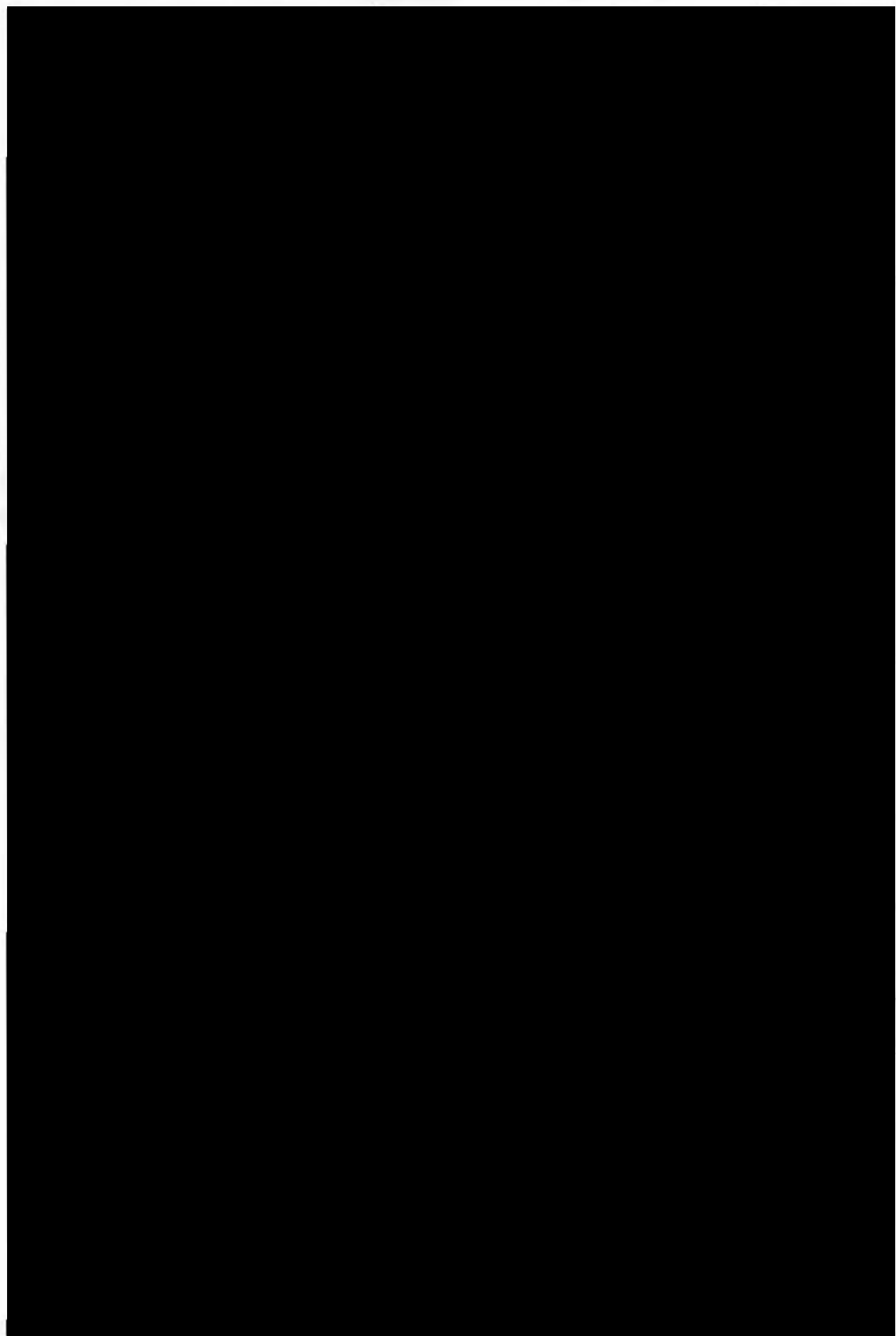

Signature

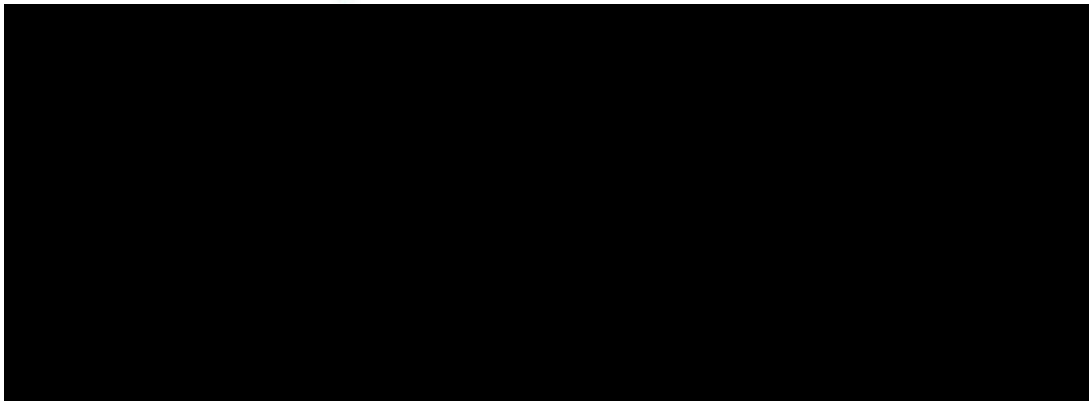
804-257-2049
Phone

Manufacturing process information may be entitled to confidential treatment

VIRKON S

CHEMICAL REACTIONS - PRODUCT CLASSIFICATION





* Appendix II

* Photocopies attached.

T R Auchincloss

T R Auchincloss, BSc, C Chem, FRSC
Chairman

TRA/SAM/17.7.87/S184

9 4
3 7
8 8

A. H. Robins Company
1407 Cummings Drive
P. O. Box 26609
Richmond, Virginia 23261-6609
Cable Robinco/TWX 7109560001
Telephone (804) 257-2000

A-H-ROBINS

Mr. Jeff Kempter
Product Manager (32)
U.S. ENVIRONMENTAL PROTECTION
AGENCY
Insecticide-Rodenticide Branch
1921 Jefferson Davis Hwy.
Arlington, VA 22202

March 30, 1989

RE: Submission of Application for Registration of New Product
VirKorr-SR

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Respectfully Submitted,

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Office of Veterinary Medicine

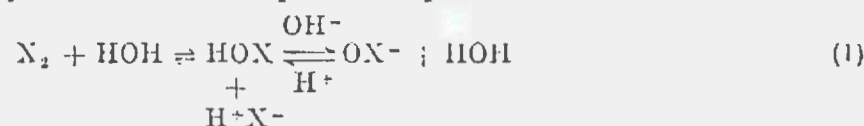
Turning to the Food Industry, the B.D.M.A. is currently working to develop an approval schedule on the lines of that used in the Milk and Dairies Industry. The Chief Medical Officer of the Ministry of Health, reporting 'on the State of the public health in England and Wales for the year 1967', includes a section on the use of detergents and sterilants in food premises. This states that 'chlorine and hypochlorites are among the best sterilants available for the food industry provided they are properly used . . .' (p. 153).

When the first men to set foot on the moon returned to earth at the successful conclusion of the Apollo 11 mission (24-7-69), an iodophor and a hypochlorite solution were chosen as two of the disinfectants for use in the decontamination process to kill possible agents of infection which might have been brought back from the moon.

B. CHEMICAL REACTIVITY

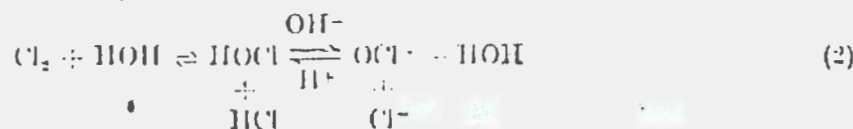
The common halogens as a group, comprising fluorine, chlorine, bromine and iodine are characterized by their extreme reactivity which is generally of an oxidizing nature. Fluorine is one of the most reactive of all the elements, and is much too reactive in terms of toxicity, irritancy and corrosiveness to be used in any disinfectant applications.

Active bromine compounds are normally also too toxic and irritant for wide use, although there are some bromine compounds which have applications in halogen mixtures (p. 164). The rapid germicidal power of the halogens is undoubtedly due to the high oxidizing reactivity by which the activity of all cellular proteins is destroyed. The active entity is either the free halogen or hypohalous acid. These two form an equilibrium which is dependent on pH.



(where X is a halogen atom)

Iodine when used as a disinfectant in iodophors (p. 174) is normally present under acid conditions, and it is the free iodine which is active (loosely complexed with nonionic surface active agents). In the case of chlorine, the solution would be unstable under acid conditions and chlorine gas would be liberated. For this reason liquid hypochlorites are normally formulated on the alkaline side of neutrality.



It is generally agreed (Sykes, 1965), that undissociated hypochlorous acid, HOCl, is the important germicidally active species, and this is in line with the improvement in germicidal activity with reduced pH (p. 150).

Referring to the equilibrium depicted in equation 2, Allen (1950) quoted figures showing 99.7% undissociated HOCl at pH 5, 73% at pH 7, and only 0.3% at pH 9. At pH values below 5, the equilibrium becomes unstable due to the formation of Cl₂, while at higher pH values the concentration of OCl⁻ ions becomes appreciable. Although it is clear that alkaline solutions of sodium hypochlorite even at pH's above 10 are germicidal (see Tables I and IV), it is not yet certain what contribution the OCl⁻ ion makes. In practice this matters little because the dynamic equilibrium ensures that HOCl is continually replaced as it is used up.

These basic mechanisms are most easily represented in the case of solutions of sodium hypochlorite, but they also apply to a range of organic N-chloro compounds (p. 162) which have been developed in recent years, and which are germicidal in solution, hydrolysing in varying degree to HOCl. There are also several examples of improved activity in halogen mixtures in which hypobromous acid and hypoiodous acid play a part; this is thought to be due to the lower degree of ionization of these two hypohalous acids, leading to more of the germicidally active entity. Further, it has been found that N-halogen organic compounds containing both bromine and chlorine may be superior to those containing only bromine or chlorine (Paterson, 1965, Table XIV).

Hypochlorous acid will liberate iodine from potassium iodide solution and titration of the iodine so liberated with sodium thiosulphate affords a rapid method for determining strengths of hypochlorite solutions (p. 144).

Halogen disinfectants tend to decompose to varying extents, on prolonged storage, the extent depending on the storage conditions.

C. HALOGENS AS STERILIZING AGENTS

Compounds in this class form one of the few groups of disinfectants which can be called sterilizing agents in the strict sense that they will kill the complete spectrum of microorganisms. The reason for this is that all forms of microorganism depend on protein both enzymatic and structural for continued life and that the halogens will oxidize and react readily, rapidly and destructively with proteins. The nucleic acids are also potential targets for the halogens. In general, vegetative cells are killed rapidly. Knox *et al.* (1948) have produced evidence to suggest that enzymes containing SH groups are especially sensitive targets for chlorine in the bacterial cell.

Bringham (1953) studied electron micrographs of bacteria treated

Accelerated Oxidation

Some peculiar effects in the bleaching of coloured goods have been investigated between 1930 and 1940 with very interesting results. It is common experience with many textile technologists that some of the yellow vat dyeings on cotton and rayon produced tendering when exposed to light under conditions which were without effect on the undyed material. Scholefield and Patel (J.S.D.C., 1929, 45, 175) found that with dyed material—certain vat yellows and oranges—treatment with hypochlorite in presence of light brought about tendering which did not occur in the dark. Derrett-Smith and Nodder (J.T.I., 1932, 23, 293) investigated the action of hypochlorite solutions over a wide range of pH values, on cotton dyed with certain vat and azoic dyes; yellow, orange and red dyes were active and tendered the cellulose, the greatest effect taking place in the neutral region. It was suggested by Scholefield and Turner (ibid., 1933, 21, 330P) that in presence of light, these active dyes can be reduced to their leuco forms, which, during oxidation (by air or other oxidising agent) bring about a strong simultaneous oxidation of the cellulose. Oxidations of this type are known to occur with a variety of organic compounds (Traube, Ber., 1881, 15, 659, 2421, 2434; 1883, 16, 123; Engleis *et al.*, see Chem. Soc. Ann. Rep., 1924, p. 109).

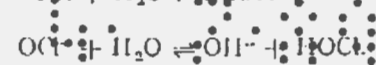
Turner, Nabar and Scholefield (J.S.D.C., 1935, 51, 5) confirmed this activating effect of reduced vat dyes on cotton in hypochlorite solutions, and found that the effect depends to a large extent on the concentration of dye on the fibre. The increased rate of oxidation of cellulose in sodium hypochlorite solution at pH 7 in presence of leuco-vat dyes is so great that for the same fluidity a number of seconds is adequate in place of the hours required in absence of dye. In presence of a third substance which is oxidised, cellulose is not protected from oxidation but is attacked with increased vigour. The suggested addition of oxalic acid to hypochlorite solutions in 1877 (G.P. 2148) certainly produced "a stronger bleaching effect" and mixtures of dichromate-oxalic acid have been used (Clibbens and Ridge, J.T.I., 1927, 18, 135) in recent times for the purpose of forming oxycellulose, which is produced much more rapidly than with dichromate-sulphuric acid.

Accelerated oxidation with hypochlorites has been examined in some detail by Kauffmann (Ber., 1932, 65, 179) who showed that the destruction of certain readily oxidisable dyes by hypochlorite is increased by the addition of small proportions of hydrogen peroxide. It was also established that cellulose itself was attacked by the accelerated oxidation of the activated hypochlorite; other agents capable of acting as activators are ammonia, chloramine, acid amides

and amino-acids. This is a departure from the usual opinion that hypochlorous acid is the agent which is responsible for attack on the fibre during uncontrolled bleaching, and is formed according to the scheme



or

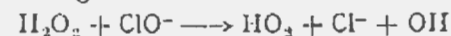


Actually, Kauffmann found that there was only slight attack on cellulose by hypochlorous acid, alone.

A number of dyestuffs are readily bleached by dilute sodium hypochlorite solution but the bleaching action is slower in presence of NaOH; the addition of hydrogen peroxide to hypochlorite solution produces rapid bleaching, but with ammonia there is a certain period of induction during which chloramine is formed, similarly with urea, when dichlorurea is formed. Chemical compounds of very different types can produce this effect, as for instance, dimethylglyoxime. The presence of these activators in hypochlorite bleach liquors may produce tendering of the cellulose.

Kauffmann is of the opinion that in bleaching, two substances are necessary, the oxidising agent and the activator; with hypochlorites the oxidising agent is the hypochlorite ion and the activator is hypochlorous acid which should not exceed about 1 mg. per litre. Bleach liquors containing higher proportions of activators are injurious to the cellulose.

This effect is interpreted on the basis of the Haber-Willstätter theory of chain-reactions, the activators being substances which form hydroxyl ions in solution. With hydrogen peroxide, for instance, the first stage is



followed by



This generates hydroxyl ions:



The process continues until the hydroxyl is used completely in the reaction



With neither catalyst nor activator, the following reaction occurs:



The decomposition of hypochlorite is a second order reaction and calculations show that maximum activity takes place at pH 7 to 8.

It will be seen, therefore, that a very considerable amount of theoretical and practical evidence is available on accelerated oxidation and activated bleach liquors, as a result of which the bleaching

A-H-ROBINS

date March 16, 1989

memo from Dr. Robert L. Miller

to Mr. H. Wayne Moran

SUBJECT: VirKon S Registration

The following listed bacteria, fungi, and viruses are not considered human pathogens:

Bacteria: *Mycoplasma gallisepticum*

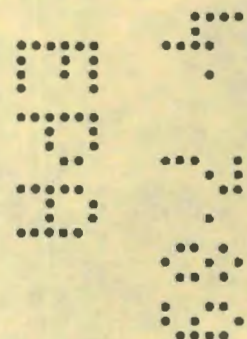
Fungi: *Aspergillus flavus*
Aspergillus fumigatus

Viruses: Newcastle Disease Virus
Infectious Bronchitis Virus
Infectious Bursal Virus
Laryngotracheitis Virus
Avian Influenza Virus
Marek's Disease Virus

R L Miller
R. L. Miller, D.V.M.

dhc

c: Dr. E. J. Corrigan



GENERAL INFORMATION

1. General Properties

VIRKON S - the most advanced virucidal disinfectant in the world - combining wide spectrum virucidal activity with excellent bactericidal and fungicidal properties.

Patents have been applied for in the USA and Japan. Initial patent granted in the UK. Patent improvements filed.

VIRKON S is unique in its composition. Its activity is based on a synergised acid peroxygen system containing a high percentage of surfactant. It can clean and sanitize in one operation.

VIRKON S is completely safe to use - non-tainting, non-corrosive, non-toxic, free from residue problems as the biocidal system is totally inorganic.

VIRKON S can be applied as an aerial spray - without discomfort to people or animals present - can be used in manual cleaning operations or applied using pressure cleaning equipment.

VIRKON S has been widely tested by the Central Veterinary Laboratory, Weybridge and the Animal Virus Research Institute, Pirbright - as a virucide - and activity confirmed against all virus families screened - affecting all species - avian, large animals, humans. It inactivates the most resistant viruses.

VIRKON S has been tested by Chester Beatty Cancer Research and proved effective against the Aids virus.

Extensive tests with various species of livestock have been carried out at Cambridge University by Dr D W B Sainsbury proving the safety and efficacy of the product.

2. Biological and Chemical Reactions

The wide spectrum biocidal activity of VIRKON S is contributed by Potassium Monopersulphate a powerful oxidising agent.

The exact nature of its biological activity is not known. It may promote oxidation of cellular material by acting on the lipo protein cytoplasmic membrane and disrupting the osmotic barrier. The exact role of the singlet oxygen is not known. The nature of the chemical reaction of VIRKON S cannot be precisely stated.

The reaction is complex and the probable chain reaction of VIRKON S is as follows:

DATA REQUIREMENT LISTING FOR THE OWNER SUBMISSION METHOD OF SUPPORT

1. PRODUCT NAME: VirKon S 5. APPLICANT'S NAME AND ADDRESS A. H. Robins Company, Inc. 1405 Cummings Drive P. O. Box 26609 Richmond, VA 23261-6609	2. EPA REG.NO/FILE SYMBOL 778- OE OR 6. APPLICATION FOR REGISTRATION DATED 3 / 25/ 89 Mo. Day Yr.	3. FORMULATOR'S EXEMPTION SELECTED YES _____ NO <u>X</u> 7. NAME OF ACTIVE INGREDIENT(S): Potassium Monopersulfate; Sodium Chloride	4. PAGE <u>1</u> of <u>3</u>
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8. DATA REQUIREMENTS		9. SOURCE OF DATA SATISFYING REQUIREMENT						10. MRID NUMBER, EPA ACCESSION NUMBER OR OTHER EPA IDENTIFYING NUMBER
8a. Regulation Part 158/ Guideline Number	8b. Name of Test	9a. Submitted by Applicant	9b. Date Submitted	9c. Submitted by another person/firm (name)	9d. Permission Letter Enclosed	9e. Public Literature	9f. N.A. or Waiver or other (Explain)	
\$158.20	PRODUCT CHEMISTRY							
61-1	Identity of ingredients	3/25/89						
61-2	Statement of composition	3/25/89						
61-3	Discussion of formation of ingredients	3/25/89						
62-1	Preliminary analysis						N.A.	
62-2	Certification of limits	3/25/89						
62-3	Analytical methods for enforcement limits	3/25/89						
63-2	Color	3/25/89						
63-3	Physical state	3/25/89						
63-4	Odor	3/25/89						
63-5	Melting point						N.A.	
63-6	Boiling point						N.A.	
63-7	Density, bulk-density, or specific gravity	3/25/89						

DATA REQUIREMENT LIST FOR THE OWNER SUBMISSION METHOD OF SUPPORT

1. PRODUCT NAME: <u>VirKon S</u> 5. APPLICANT'S NAME AND ADDRESS <u>A. H. Robins Company, Inc.</u> <u>1405 Cummings Drive</u> <u>P. O. Box 26609</u> <u>Richmond, VA 23261-6609</u>	2. EPA REG.NO/FILE SYMBOL <u>778-050R</u> 6. APPLICATION FOR REGISTRATION DATED <u>3 / 25 / 89</u> Mo. Day Yr.	3. FORMULATOR'S EXEMPTION SELECTED YES _____ NO <u>X</u> 7. NAME OF ACTIVE INGREDIENT(S): <u>Potassium Monopersulfate, Sodium Chloride</u>	4. PAGE <u>2</u> of <u>3</u>
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8. DATA REQUIREMENTS		9. SOURCE OF DATA SATISFYING REQUIREMENT						10. MRID NUMBER, EPA ACCESSION NUMBER OR OTHER EPA IDENTIFYING NUMBER
8a. Regulation Part 158/ Guideline Number	8b. Name of Test	9a. Submitted by Applicant	9b. Date Submitted	9c. Submitted by another person/firm (name)	9d. Permission Letter Enclosed	9e. Public Literature	9f. N.A. or Waiver or other (Explain)	
\$158.20	PRODUCT CHEMISTRY (Continued)							
63-8	Solubility						N.A.	
63-9	Vapor pressure						N.A.	
63-10	Dissociation constant						N.A.	
63-11	Octanol/water partition coefficient						N.A.	
63-12	pH	3/15/89						
63-13	Stability						N.A.	
63-14	Oxidizing/reducing reaction	3/25/89						
63-15	Flammability						N.A.	
63-16	Explosibility	3/25/89						
63-17	Storage stability	3/25/89						
63-18	Viscosity						N.A.	
63-19	Miscibility						N.A.	

DATA REQUIREMENT LISTING FOR THE PAPER SUBMISSION METHOD OF SUPPORT

1. PRODUCT NAME: VirKon S 5. APPLICANT'S NAME AND ADDRESS A. H. Robins Company, Inc. 1405 Cummings Drive P. O. Box 26609 Richmond, VA 23261-6609	2. EPA REG.NO/FILE SYMBOL 778-020R 6. APPLICATION FOR REGISTRATION DATED 3 / 25 / 89 Mo. Day Yr.	3. FORMULATOR'S EXEMPTION SELECTED YES <u> X </u> NO <u> </u> 7. NAME OF ACTIVE INGREDIENT(S): Potassium Monopersulfate, Sodium Chloride	4. PAGE <u> 3 </u> of <u> 3 </u>
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8. DATA REQUIREMENTS		9. SOURCE OF DATA SATISFYING REQUIREMENT						10. MRID NUMBER, EPA ACCESSION NUMBER OR OTHER EPA IDENTIFYING NUMBER
8a. Regulation Part 158/ Guideline Number	8b. Name of Test	9a. Submitted by Applicant	9b. Date Submitted	9c. Submitted by another person/firm (name)	9d. Permission Letter Enclosed	9e. Public Literature	9f. N.A. or Waiver or other (Explain)	
\$158.20	PRODUCT CHEMISTRY (continued)							
63-20	Corrosion characteristics	3/25/89						
63-21	Dielectric breakdown voltage						N.A.	
\$158.135	TOXICOLOGY							
81-1	Acute oral LD-50, rat	3/25/89						
81-2	Acute dermal LD-50	3/25/89						
81-3	Acute inhalation LC-50, rat	3/25/89						
81-4	Primary eye irritation, rabbit	3/25/89						
81-5	Primary dermal irritation	3/25/89						
81-6	Dermal sensitization	3/25/89						



United States Environmental Protection Agency
Washington, DC 20460

Certification with Respect to Citation of Data

Form Approved
OMB No. 2070-0060
Approval expires 9-30-90

Applicant's Name and Address

A. H. Robins Company, Inc.
1405 Cummings Drive
P. O. Box 26609
Richmond, VA 23261-5609

EPA File Symbol/Registration Number

778-~~OE~~ OR

Product Name

VirKon S

Date of Application

3/25/89

1. This application is supported by all data submitted or cited in the application. In addition, if cite-all options are indicated, this application is supported by all data in the Agency's files that concern the properties or effects of this product or of any other product that is identical or substantially similar, and that is one of the types of data that would be required to be submitted if this application sought the initial registration of a product of identical or similar composition and intended uses under the data requirements in effect on the date of approval of this application.

2. I certify that, for each study cited in support of this application for registration that is an exclusive use study, I am the original data submitter, or have obtained the written permission of the original data submitter to cite that study.

3. I certify that, for each study cited in support of this application for registration that is not an exclusive use study:

I am the original data submitter; or I have obtained the written permission of the original data submitter to cite that study; or

I have notified in writing the companies who have submitted data I have cited to support this application and have offered to: (a) Pay compensation for those data in accordance with section 3(c)(1)(D) and 3(c)(2)(D) of the Federal Insecticide, Fungicide and Rodenticide Act; and (b) Commence negotiations to determine which data are subject to the compensation requirement of FIFRA and the amount and terms of compensation due, if any. The companies I have notified are: *(Check one)*

☐ All companies listed on the Pesticide Data Submitters List for all active ingredients contained in my product (cite-all method or cite-all option under Selective Method). *(Also sign the General Offer to Pay Statement below.)*

☒ Those companies who have submitted the studies which I have cited (Selective method).

Signature

Name and Title Mgr., Regulatory
Affairs, Pet Care Products R&D
H. Wayne Moran

Date

3/25/89

General Offer to Pay: I hereby offer and agree to pay compensation to other persons, with regard to the approval of this application, to the extent required by FIFRA sec. 3(c)(1)(D) and 3(c)(2)(D).

Signature

Name and Title Mgr., Regulatory
Affairs, Pet care Products R&D
H. Wayne Moran

Date

3/25/89



United States Environmental Protection Agency
Washington, DC 20460

Certification with Respect to Citation of Data

Form Approved
OMB No. 2070-0060
Approval expires 9-30-90

Applicant's Name and Address

A. H. Robins Company, Inc.
1405 Cummings Drive
P. O. Box 26609
Richmond, VA 23261-6609

EPA File Symbol/Registration Number

778-OR

Product Name

VirKon S

Date of Application

3/25/89

1. This application is supported by all data submitted or cited in the application. In addition, if cite-all options are indicated, this application is supported by all data in the Agency's files that concern the properties or effects of this product or of any other product that is identical or substantially similar, and that is one of the types of data that would be required to be submitted if this application sought the initial registration of a product of identical or similar composition and intended uses under the data requirements in effect on the date of approval of this application.

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3. I certify that, for each study cited in support of this application for registration that is not an exclusive use study:

I am the original data submitter; or I have obtained the written permission of the original data submitter to cite that study; or

I have notified in writing the companies who have submitted data I have cited to support this application and have offered to: (a) Pay compensation for those data in accordance with section 3(c)(1)(D) and 3(c)(2)(D) of the Federal Insecticide, Fungicide and Rodenticide Act; and (b) Commence negotiations to determine which data are subject to the compensation requirement of FIFRA and the amount and terms of compensation due, if any. The companies I have notified are: (Check one)

☐ All companies listed on the Pesticide Data Submitters List for all active ingredients contained in my product (cite-all method or cite-all option under Selective Method). (Also sign the General Offer to Pay Statement below.)

☒ Those companies who have submitted the studies which I have cited (Selective method).

Signature

Wayne Moran

Name and Title Mgr., Regulatory
Affairs, Pet Care Products R&D
H. Wayne Moran

Date

3/25/89

General Offer to Pay: I hereby offer and agree to pay compensation to other persons, with regard to the approval of this application, to the extent required by FIFRA sec. 3(c)(1)(D) and 3(c)(2)(D).

Signature

Wayne Moran

Name and Title Mgr., Regulatory
Affairs, Pet care Products R&D
H. Wayne Moran

Date

3/25/89



United States Environmental Protection Agency
Office of Pesticide Programs (TS-767)
Washington, DC 20460

OPP Identifier Number

Application for Pesticide: ☒ Registration
☐ Amendment

112980

Section I

1. Company/Product Number 778-0E-OR 2. Date March 25, 1989 3. Product Manager Jeff Kempter (32) 4. Proposed Classification ☒ General ☐ Restricted

5. Name and Address of Applicant (Include ZIP Code)

A. H. Robins Company, Inc.
1405 Cummings Drive
P. O. Box 26609
Richmond, VA 23261-6609

☐ Check if this is a new address

6. Product Name

VirKon S

Section II - Amendment Information

1. Subject ☐ Resubmission in response to Agency letter ☐ Final printed label in response to Agency letter ☐ Other (explain below) Date of Letter

Section III

1. Material This Product Will Be Packaged In
Child-Resistant Packaging ☒ Yes ☐ No
Unit Packaging ☐ Yes ☒ No
If "Yes," Unit package wgt No. per container
Water-Soluble Packaging ☐ Yes ☒ No
If "Yes," Package weight No. per container
2. Type of Container ☒ Metal ☐ Plastic ☐ Glass ☐ Paper ☐ Other (Specify)
3. Location of Net Contents Information ☒ Label ☐ Container 4. Size(s) of Retail Container 5 kg
5. Location of Label Directions ☒ On Label ☐ On material accompanying product
6. Manner in Which Label Is Affixed To Product ☐ Lithograph ☒ Paper glued ☐ Other (Specify) ☐ Stenciled

Section IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application).
Name H. Wayne Moran
Title Mgr., Regulatory Affairs
Pet Care Products R&D Telephone No. (Include Area Code) (804) 257-2049
6. Date Application Received (Stamp)
Certification
I certify that the statements I have made on this form and all attachments thereto are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.
2. Signature H. Wayne Moran
3. Title Mgr., Regulatory Affairs, Pet Care Products R&D
4. Typed Name H. Wayne Moran
5. Date Signed 3/25/89

Instructions

General

This form is to be used for all applications for new and amended registrations for pesticide products.

In order to process an application for new registration submitted on this form, the following material must accompany the application:

1. Offer to Pay Statement (EPA Form 8570-22, -23, or -24). (If not exempted by 40 CFR 162.9-1(b).)
2. Confidential Statement of Formula (EPA Form 8570-4).
3. Five copies of draft labeling.
4. Three copies of any data submitted.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8 1/2 x 11 inch paper or as a mockup of the proposed label. If prepared as a mockup it should be constructed in such a way as to facilitate storage in an 8 1/2 x 11 inch file. Mockup labels significantly smaller than 8 1/2 x 11 inches should be mounted on 8 1/2 x 11 inch paper for submission.

Submission of Data - Data submitted in support of this application must be submitted in three copies. In order to facilitate review, each type of data submitted must be bound separately, and clearly identified on the front cover including the date submitted.

A copy of the application form and a copy of the label should be bound in each separate volume of the data.

All Data For Which Claims of Confidentiality Are Asserted Must Be Submitted, Bound Separately and Clearly Marked As Such

Specific

Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Section I, III, and IV must be completed by the applicant. For applications submitted in connection with amended registration actions, Sections I, II, and IV must be completed by the applicant.

Block A - Check the appropriate action for which you are submitting this form.

Section I - This Section must be completed for both Registration and Amended Registration actions.

1. **Company/Product Number** - Insert your company number, if one has been assigned. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If application is for an amendment, insert the registrant number of the product.
2. **Date** - Fill in the appropriate date.
3. **Product Manager** - If known, fill in the name and number of the Product Manager.
4. **Proposed Classification** - Specify the proposed classification for this product.
5. **Name and Address of Applicant** - The name of the firm or person and address shown in your application is the person or firm to whom registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters.

An applicant Not residing in the United States must have an authorized agent residing in the United States to act for

them in all registration matters. The name and complete mailing address of such an agent must accompany this application.

6. **Product Name** - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.

Amendment Information

Section II - This Section must be completed for all applications submitted in connection with Amended Registration.

1. **Subject of Amendment** - Check the appropriate block, and provide a brief explanation of the purpose(s) for the amendment, such as: "the addition of a site, pest, or crop"; "to change inert ingredient"; "general label revisions of precautionary statements," etc.

Packaging and Container Information

Section III - This Section must be completed for all applications submitted in connection with New Registration.

1. **Type of Packaging** - Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
2. **Type of Retail Container** - Indicate type of container in which product will be marketed.
3. **Location of Net Contents** - Specify the net contents of all retail containers for your product.
4. **Size(s) of Retail Container** - Specify the net contents of all retail containers for your product.
5. **Location of Use Directions** - Indicate the location of the use directions for your product.
6. **Manner in which label is affixed to product** - Indicate the method product labeling is attached to retail container.

Contact Point

Section IV - This Section must be completed for all Registration and Amended Registration applications.

- 1-5. Self-explanatory.
6. EPA Use Only.